



Competing by Saving Lives:

How Pharmaceutical and Medical Device Companies
Create **Shared Value** in Global Health

Foreword by Michael E. Porter

The background features a large, light blue watermark of the FSG logo, which consists of the letters 'FSG' in a bold, sans-serif font, with a large, thin, curved line arching over the letters.

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Foreword

Shared value is inherent in health technology companies.

By Michael E. Porter, Professor
Harvard Business School and Co-Founder, FSG



Pharmaceutical and medical device companies, the focus of this report, create both economic and societal value when they provide products that tackle important health problems. Not all fields have clear opportunities to create competitive advantage while simultaneously advancing such a vital societal goal as better health. However, the opportunity for these industries to create shared value is far greater.

Capitalism faces a watershed moment.

Now is the time for the private sector to demonstrate its potential for both economic growth and societal purpose. As companies create shared value by meeting social needs, the capabilities and scalability of business is unleashed on societal challenges such as the rising burden of non-communicable diseases in the developing world. Government, local health systems, and the nonprofit sector will play leadership roles in prevention and treatment. But capitalism, guided by the pursuit of shared value, will take on a greater role in addressing the global burden of disease.

CREATING SHARED VALUE

“Companies create shared value by creating economic value and societal value simultaneously. There are three distinct ways to do this: by reconceiving products and markets, redefining productivity in the value chain, and building supportive industry clusters at the company’s locations.”

Michael E. Porter and Mark R. Kramer, “Creating Shared Value,” *Harvard Business Review*

Historically, pharmaceutical and medical device companies built their businesses by serving affluent markets in North America, Europe, and Japan. In the process, they have overlooked the unmet health needs of billions of underserved patients, and with it, huge opportunities for innovation and growth.

Fortunately, there are promising signs of change. Some pharmaceutical and medical device companies are prioritizing previously underserved patients and markets. Rather than seeing efforts in assisting lower income customers as corporate social responsibility and philanthropy, companies are transforming their products, pricing, manufacturing, distribution, and marketing to profitably meet previously unmet needs. There are encouraging signs that serving these new markets can be profitable, and multiply the size of the available market.

This report follows the January 2011 release of the article “Creating Shared Value” in *Harvard Business Review*. It represents the first of a series of studies that will focus on shared value within particular sectors.¹ The report seeks to inform and inspire companies in the pharmaceutical and medical device industries, while providing insights that can assist companies

in other fields create and implement shared value. We hope that this study spurs leaders from the private sector, civil society, investors, and government in new approaches to addressing health problems through new management thinking, innovations in business models, and cross-sector collaboration.

Executive Summary

A new dynamic is changing the basis of competition in the pharmaceutical and medical device industries.

Increasingly, companies are seeing opportunities to meet the needs of underserved populations in low- and middle-income countries, where they once saw little commercial interest. This report highlights how pharmaceutical and medical device companies are **creating shared value in global health** by enhancing their competitiveness while simultaneously addressing the global burden of disease — often working in partnership with governments, funders, and nonprofit organizations.

Background

- In return for investing in risky R&D to develop revolutionary, life-saving technologies, society provides pharmaceutical and medical device firms with intellectual property protections that reward success. While this social contract has worked well for the world's richest nations, until recently, the underserved in Asia, Africa, and Latin America have generally been an afterthought. Global health advocates have called for better adapted products and lower prices, to which companies have responded. But until recently, efforts have largely been philanthropic or reputation-driven.
- In the last decade, this picture has begun to change. Developed markets are coming under pressure as traditional health systems are scrutinizing costs as never before. At the same time, R&D productivity has fallen, particularly for pharmaceutical firms. This is forcing companies to reconsider opportunities in low- and middle-income countries they may previously have overlooked. In parallel, newly recognized market opportunities are emerging around the enormous unaddressed health needs in these countries. Emerging markets could account for nearly half of worldwide revenues for pharmaceutical companies by 2012,² and these areas

are expected to account for 75 percent of industry growth over the coming decade.³

The Shared Value Opportunity

- Companies create shared value in global health when they compete on the basis of improving health outcomes for the underserved. Rather than competing for market share among well-funded payers and wealthy patients, companies view their success in terms of their ability to improve health outcomes by building and serving new markets. To achieve that success, companies need to systematically and relentlessly uncover new, unmet needs, and find new and better ways to address them at scale.
- Low- and middle-income countries have vast unmet needs. The top five non-injury causes of death in 2008 claimed nearly 29 million lives in low- and middle-income countries, compared with just 6.6 million in high-income countries. Southeast Asian and African countries, in particular, face a double burden of infectious diseases and non-communicable diseases (NCDs), such as cardiovascular disease, diabetes, and cancer.
- Meeting these needs is challenging, even for sophisticated corporations. Missing skills and knowledge, limited market information, ineffective regulation, inadequate health systems, and limited funding or inability of patients to pay present firms with huge barriers to entry. To overcome these barriers, companies are investing in three levels of shared value (see Figure 1).
- Efforts to create shared value across the three levels are mutually reinforcing. Productive and lower-cost value chains are essential to introducing redesigned product portfolios to underserved

Figure 1: Levels of Shared Value Creation for Pharmaceutical and Medical Device Companies

1 Reconceiving Products and Markets	2 Redefining Productivity in the Value Chain	3 Enabling Local Cluster Development
<ul style="list-style-type: none"> • R&D for drugs, vaccines, and devices that fill unmet health needs • Adaptation of existing products to reduce complexity and cost • Tailored product offerings to meet local market conditions 	<ul style="list-style-type: none"> • Collaborative and homegrown R&D to reduce cost and risk • Efficient, local supply chains and manufacturing to reduce production costs • Locally-adapted sales and distribution to penetrate new markets and better meet patient needs 	<ul style="list-style-type: none"> • Behavior-change campaigns to increase the sophistication of demand for health care • Health system strengthening to enable delivery of needed products and services • Advocacy and capacity building to strengthen policy and the regulatory environment

markets. Strong clusters can enable firms to serve population segments that were previously out of reach, and can open up new, lower-cost manufacturing and distribution options. Leading firms are beginning to design multi-level approaches to harness this multiplier effect, though the right combination will be unique to a particular company and market.

- Stakeholders and shareholders are warming to shared value. Global health stakeholders desire a move away from charity to more sustainable and scalable ways to provide drugs, vaccines, and medical devices to patients in underserved markets. And these stakeholders want to partner — in a recent survey, 79 percent of nonprofit organizations reported that pharmaceutical and medical device companies are essential partners in the effort to achieve their missions.⁴ Mainstream investors are adopting a wait-and-see attitude to company engagement in low- and middle-income countries. More socially-minded investors and analysts are paying increasing attention to companies reaching the underserved.
- Shared value cannot address all global health needs. Systemic market failures exist in health technology, notably around neglected diseases, where needed

products and services are not being developed or delivered on a commercial basis due to the inability of patients to pay. A shared value frontier defines the boundary of such failures.

- However, companies are innovating to serve patients at the shared value frontier, where health systems are notably deficient or patients lack the ability to pay. As local complexities increase, companies are employing sophisticated combinations of shared value approaches. In the longer term, there is good evidence to believe that some companies will expand the shared value frontier further into poorer populations.
- Corporate philanthropy and external funders, such as governments and foundations, can also bridge the shared value frontier. Corporate philanthropy can accelerate existing shared value initiatives — often through strengthening health systems — or incubate new projects in locations where companies do not have commercial operations. Governments and private funders also offer incentives that reduce risk for investments in R&D efforts or establish commitments for future drug or vaccine purchases.

Implementing Shared Value for Global Health

Common success factors are emerging among companies as they implement shared value. Leading companies are following five principles:

- **Focused and determined leadership at the CEO and country levels.** Companies that excel at shared value have CEOs and country-level managers who bring a compelling vision and personal involvement to expansion efforts in low- and middle-income markets. Without leadership, pharmaceutical and medical device companies stumble and resort to more traditional, charity-led engagement with patients in low- and middle-income countries.
- **A culture of innovation and learning reflected in structures and incentives.** Cross-functional teams can help to coalesce, prioritize, and coordinate shared value approaches that straddle R&D, government affairs, and marketing. Companies have also created separate social innovation units that directly manage shared value initiatives.
- **New approaches to measurement that track the link between business value and improved patient lives.** Such metrics offer companies a way to understand what works to create shared value, and allows them to assess the potential of new investments, to allocate resources, and to set relevant incentives. While few companies have developed robust systems to measure shared value, early adopters are starting to use such information to make key management decisions, and are seeing improved performance as a result.
- **New skills in identifying and acting on unmet health needs.** To penetrate new markets, companies require employees with on-the-ground knowledge of health needs among underserved patients, an ability to translate needs into business strategy, and strong stakeholder-engagement capabilities.
- **New partnerships for shared value insights and implementation.** Companies are looking to a new set of partners to help with shared value strategy-setting and specific competencies in adapting products, improving productivity and cost effectiveness, and strengthening the competitive context. Many of these partners are nonprofits, which marks a shift from prior roles as corporate philanthropic grantees.



Catalyzing Greater Shared Value for Global Health

The following recommendations for companies and stakeholders can catalyze greater experimentation in shared value for the benefit of companies, patients, and health systems.

Recommendations for Companies

→ *Shift from defensive to affirmative engagement with patients in low- and middle-income countries.*

Companies should be transparent with global stakeholders about their ambitions in low- and middle-income countries. Specific shared value approaches, motivated by profit, can be articulated for the benefit of the global health field. Where shared value approaches are not presently feasible, companies can explain the role of their philanthropic contributions and the intentions of partnerships with government and private funders.

→ *Innovate and capture knowledge on health product delivery.*

As companies learn more about how to market drugs, vaccines, and medical devices to the hard-to-reach and poorly-served populations, lessons should be shared, within the limits of competitive confidentiality. Promising multi-sector models for sharing best practices on health product distribution and disease awareness-building are emerging.

→ *Experiment with shared value measurement to spur learning and innovation.*

Pharmaceutical and medical device companies should be in a position to lead other industries on measuring shared value, due to the inherent alignment between the increased sales of their life-enhancing products and meeting patient health needs. Companies should set, specific, forward-looking targets for populations, behavior changes, health system strengthening and disease indicators, and should measure progress towards them.

→ *Invest early to gain first-mover advantage.*

Companies that invest ahead of their rivals, such as GlaxoSmithKline in India and Novo Nordisk in China, find themselves with a sizable competitive advantage as new markets develop and mature.

Recommendations for Global Health Stakeholders

- Context-setting institutions, such as governments and civil society, can monitor the results of shared value initiatives, including patient outcomes and health system improvements. Specifically, advocacy-oriented organizations have a role to play in ensuring that health technology companies develop strategies to expand access to poorer patients at the frontier of shared value in Africa and Asia. Organizations that provide information and insight on unmet health needs can stimulate more immediate shared value opportunities through patient research, value chain analysis, and health system auditing. Organizations that partner with companies to implement shared value strategies can be more proactive in offering their services. Lastly, funders can incentivize the private sector to scale-up delivery of health products to patients in remote locations or where health systems are particularly deficient.

Introduction

Shared Value in Global Health

Pharmaceutical and medical device companies create shared value in low- and middle-income countries when they generate returns for the business and address unmet health needs at scale.



Saving lives, and reducing suffering and ill-health, are the purpose for which pharmaceutical and medical device companies exist, and the ultimate source of their value creation.

In high-income countries, companies have contributed to enormous improvements in health and well-being and they have prospered as a result. Low- and middle-income countries have benefitted to a much lesser extent, and have often been an afterthought for the leading firms. While a strong moral case has long been made for health technology firms to address unmet health needs in low- and middle-income countries, until recently, the commercial opportunity has been much less apparent.

Over the last decade, global health activists, representing the interests of the underserved, have been successful in pushing equitable access onto corporate agendas. Leading companies responded with dozens of thoughtful, philanthropic partnerships to increase access to their products. While these partnerships introduced companies to unmet health needs, they did little to change the products sold, the people selling them, and investments in health systems. The disease burden in some low- and middle-income countries was perceived as a market failure, and the attendant health product R&D and delivery barriers were seen as too high to overcome.



In a marked change, pharmaceutical and medical device firms are now seizing opportunities to create shared value. They are beginning to realize that, in many cases, meeting some needs of the underserved in low- and middle-income countries may prove an important source of future growth and profitability. Likewise, the global health field recognizes that firms can have more impact when they act as businesses to solve health problems.

The future can be seen, for example, in the commercially-sustainable Arogya Parivar business of

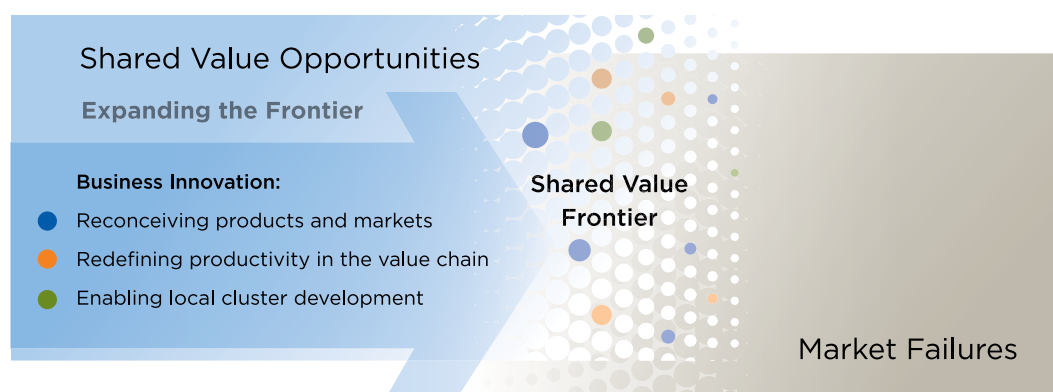
Novartis, which reaches 42 million underserved people — many with incomes below \$5 per day — in 33,000 villages across 10 Indian states. To create shared value, the company tailored its portfolio of products and services, reinvented its approach to sales and distribution, and invested in health-worker training and patient education. In the process, it contributed significantly to the well-being of patients and health systems.

Such innovation cannot address every global health challenge. Systemic market failures exist in health technology, notably around neglected diseases, where needed products and services are not being developed or delivered on a commercial basis due to the inability of patients to pay. These market failures are a genuine issue that shared value cannot address, at least in the short term.

Yet, recognition is growing that market failures do not explain all unmet health needs in low- and middle-income countries.

Companies can reach many people — often poor but not destitute — who have limited access to health care today, but who could viably be reached through shared value approaches. For example, by 2030, 87 million individuals are projected to have diabetes in India. The private sector could serve a significant number of these patients.⁵ Moreover, the shared value frontier that marks the boundary between new markets and true market failure is not fixed. Today's genuine market failures are often tomorrow's shared value opportunities (see Figure 2 below).

Figure 2: The Shared Value Frontier



Most corporations are still at an experimental stage of shared value. But early findings are revealing commercial, patient, and health system benefits. For example, two-thirds of BD's (Becton, Dickinson and Co.) growth will come from low- and middle-income countries in 2011.⁶ Novo Nordisk has saved an estimated 140,000 life years (as of year-end 2010) since entering the Chinese market in the mid-1990s, through improved products for diabetes treatment, increased physician training, and greater patient education.⁷ In the process, it has achieved a 63 percent market share in a market worth more than \$1 billion in 2010 and has grown in value at nearly 40 percent per year.⁸

The challenge for the health technology sector, and for the global health field as a whole, is to accelerate these trends. Companies increasingly recognize the potential to create shared value, but they are still searching for the best ways to invest and act. Promising examples exist, particularly in China and India, which have developed into test beds for shared value in global health. This is due to the size and growth rates of their markets, as well as strong manufacturing clusters that can deliver the volumes needed for success. Market penetration is advancing more slowly within the lower-income and rural markets of India and China, while commercial investment is still at a nascent stage in less developed countries in Asia and Sub-Saharan Africa — although signs point to progress there, too.

This report explores how pharmaceutical and medical device companies are starting to seize shared value opportunities, and how, in doing so, they can be authentic partners in improving health outcomes for the underserved. It builds on the work of many others, such as C.K. Prahalad, and is indebted to existing concepts of inclusive business models in developing countries.⁹ Our analysis is informed by an extensive literature review, secondary research on health technology firms, and more than 70 expert interviews (see the bibliography and list of interviewees).

The report covers new ground, offering a framework for specific firm-level actions and collaborations. We illustrate how companies are creating shared value by reconceiving their products and

DEFINITIONS, SCOPE, AND METHODOLOGY

Definitions and Scope

This paper's title and focus, "Competing by Saving Lives: How Pharmaceutical and Medical Device Companies Create Shared Value in Global Health," encompasses two specific concepts.

Michael Porter and Mark Kramer defined the idea of **creating shared value** as, "**enhanc[ing] the competitiveness of a company while simultaneously advancing the economic and social conditions in the communities in which it operates.**"¹⁰ While we recognize that many health-related industries contribute to public health, we have chosen to focus on pharmaceuticals and medical devices, which we refer to collectively as the **health technology sector**. We have selected these industries because they are newly motivated to enter low- and middle-income markets, and their specific market entry approaches have not yet been documented. We acknowledge the inherent differences in how the two industries function, yet, the range of shared value opportunities in low- and middle-income countries is similar. In particular, we concentrate on large, multinational corporations that have been at the center of dialogue in recent years and have the resources to act at scale (see Figure 3 for list of top 10 pharmaceutical and medical device companies by revenue). Other publications document valuable lessons from small- and medium-scale social enterprises.¹¹

Global health is defined as the science and practice of "improving health and achieving equity in health for all people worldwide."¹² For reasons of scope, we have chosen a narrower definition, with the same spirit. Specifically, we consider the health needs of underserved populations in low- and middle-income countries, according to the World Bank country classification system.¹³ We acknowledge that unmet health needs also exist in developed countries. However, we have chosen to focus on low- and middle-income countries because they account for a disproportionate amount of the global disease burden, their resources to address the challenge are much more limited, and until recently, they have garnered little attention from most pharmaceutical and medical device companies.

While we believe the concept is uncontroversial, the term "underserved populations" has not been explicitly defined in the literature.¹⁴ We therefore use the following working definition throughout the report: **Underserved populations are people who, through poverty, poor health technology coverage, or weak health systems, lack access to health services that meet their needs.**

...the global health field recognizes that firms can have more impact when they act as businesses to solve health problems.

markets; redefining productivity in their value chains; and strengthening their clusters — the ecosystems of supporting industries, competitors, health systems, governments, and civil society actors in which they operate. We also discuss five key principles for how companies can plan, implement, and manage such efforts. Ultimately, we seek to advance the discussion about the health technology sector's role in global health and trigger further action among companies and stakeholders alike.

Methodology

In formulating the conclusions laid out in this paper, FSG conducted or developed a literature review of more than 90 reports, secondary research on pharmaceutical

and medical device companies, and 70 interviews with industry leaders, government and funder representatives, and other stakeholders.

Figure 3: Top 10 Companies by Revenue per Segment (2010)

Top 10 Originator Pharmaceutical Companies	2010 Sales (Bn)	Top 10 Generic Pharmaceutical Companies*	Q1-Q2 2010 Sales (Bn)**	Top 10 Medical Device Companies	2010 Sales (Bn)***
Pfizer	\$ 55.6	Teva	\$ 11.0	Johnson & Johnson	\$ 26.5
Novartis	\$ 46.8	Novartis (incl. Sandoz)	\$ 7.2	GE Healthcare	\$ 16.8
Merck & Company	\$ 38.5	Mylan	\$ 6.2	Siemens	\$ 16.1
Sanofi-Aventis	\$ 35.9	Abbott (incl. Piramal)	\$ 3.4	Medtronic	\$ 15.8
AstraZeneca	\$ 35.5	Pfizer	\$ 3.2	Philips Healthcare	\$ 8.7
GlaxoSmithKline	\$ 33.7	GlaxoSmithKline	\$ 3.0	Covidien	\$ 8.5
Roche	\$ 32.7	Unknown Manufacturer	\$ 3.0	Roche	\$ 8.4
Johnson & Johnson	\$ 26.8	Merck & Company	\$ 2.7	Boston Scientific	\$ 7.8
Abbott	\$ 23.8	Sanofi-Aventis	\$ 2.8	Abbott	\$ 7.8
Eli Lilly and Company	\$ 22.1	Watson	\$ 2.5	BD	\$ 7.4

Source: IMS Health Midas, December 2010.

* Includes originator pharmaceutical companies with presence in the generics drug market through subsidiary companies, acquisitions, or in-licensing agreements.

** Based on IMS sales data through Q2 2010.

Note: Other well known manufacturers, Cipla (\$942 M) and Dr. Reddy (\$1.2 Bn FY10), fall below the list in revenue.

Source: IMS Consulting Group report to the Bill & Melinda Gates Foundation, 2011.

*** Estimated device-only revenue.

Source: "The Global Medical Device Market, 2nd Edition," Kalorama Information, April 2011.

Background

A common assumption, that companies have little commercial interest in meeting the health needs of the world's underserved in low- and middle-income countries, is being disproven by changing populations, disease burdens, and economic conditions. Newly-recognized market opportunities for companies are emerging around the enormous unaddressed health needs of low- and middle-income countries.



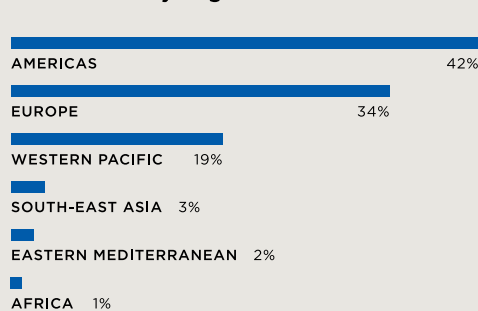
When the pharmaceutical and medical device industries became fully established following World War II, they embodied the idea of **shared value**.

Companies invested in risky R&D to develop revolutionary, life-saving technologies; in return, society provided them with intellectual property protections that rewarded success.¹⁵ As a result, society gained from transformative advances in health technology, ranging from antibiotics to artificial hearts. These innovations have helped to raise life expectancy in most developed countries by more than a decade since 1945.¹⁶ Companies have also benefited: In 2011, the 18 health technology firms in the Fortune 500 generated more than \$350 billion in revenues and employed more than 700,000 people.¹⁷

Over time, this social contract has been called into question. Health technology companies have focused ever more narrowly on developing similar products for well-understood indications in safe, bankable markets. The global poor were generally an afterthought, even as the World Health Organization (WHO) and others moved to recognize their health needs as a human right. The result has been that even as lives in the developed world have been transformed, the underserved in low- and middle-income countries have been left behind (see Figure 4).¹⁸

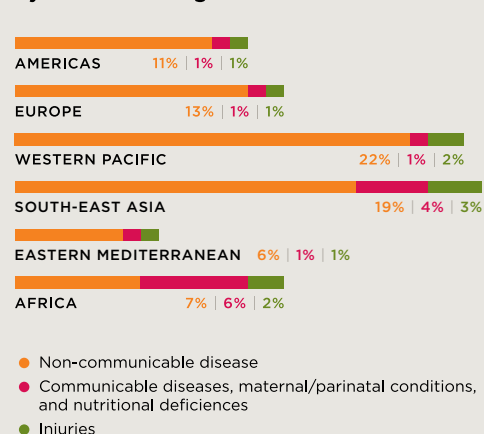
Figure 4: Comparison of Health Spending and Mortality by Region

Distribution of Global Spending on Medicine by Region



Source: World Health Organization

2030 Projected Deaths Distributed by Cause and Region



In 2008, cardiovascular disease led to more than 17 million deaths globally — the single biggest cause of mortality. Yet only 4 percent of these deaths occurred in high-income countries, while low-income countries accounted for 42 percent.¹⁹ Moreover, just 5 percent of global spending on cancer occurs in low- and middle-income countries, even though they account for almost 80 percent of the cancer burden in terms of life-years lost.²⁰ This burden is felt at least as much in large middle-income markets like India and China as it is in less developed countries. Recent estimates suggest that more than twice as many poor people live in South Asia as in Africa.²¹

Nonprofit organizations, multilaterals, and foundations stepped in to try to fill the gap, in the absence of industry engagement. Organizations like the Treatment Action Campaign in South Africa, *Médecins Sans Frontières* (MSF), and Oxfam International progressively increased pressure on pharmaceutical companies to supply essential products to low- and middle-income countries at reduced cost, and to increase marketing transparency. Pharmaceutical companies responded to this pressure with philanthropy. In the best cases, such as Merck's Mectizan donation program and Pfizer's Global Health Fellows program, companies leveraged corporate assets to address specific health issues. In many other cases, however, companies concentrated on being seen to do the right thing — or, at least, on not being seen doing the wrong thing — rather than on more concerted efforts to address the underlying problems of access, quality, and cost of health products. Moreover, philanthropic engagements were accompanied by controversial efforts to protect intellectual property rights, such as the Pharmaceutical Manufacturers Association of South Africa's decision in 1998 to sue the government of South Africa over its medicines policies on behalf of 39 companies.

More recently, companies' philanthropic efforts have grown in volume and sophistication, particularly during the last ten years. In 2009, the value of pharmaceutical donations and corporate social responsibility programs directed toward developing countries was estimated to be \$3.4 billion — a two-fold increase since 2005.²² In 2010, 102 R&D projects for the so-called “diseases of the developing world” (the ten diseases prioritized by the Programme for Research and Training in Tropical Disease) were underway directly by pharmaceutical companies or in partnerships with a Product Development Partnership.²³ In 2006, 49 similar R&D projects were sponsored by pharmaceutical companies.²⁴ Initiatives such as the Access to Medicine Index, the GAVI Alliance, and Advanced Market Commitments have begun to create a pull for companies to engage on global health issues, complementing the push for public health advocacy. These initiatives have been effective in beginning to bridge the market failure around neglected tropical diseases and other diseases of the poor, and they will continue to be necessary for many years to come.

Nevertheless, such efforts have been underpinned by a common assumption, shared by the industry and its stakeholders: companies have little commercial interest in meeting the health needs of the world's underserved in low- and middle-income countries. At best, both sides have seen companies' role as being suppliers to the global health field. Civil society and government

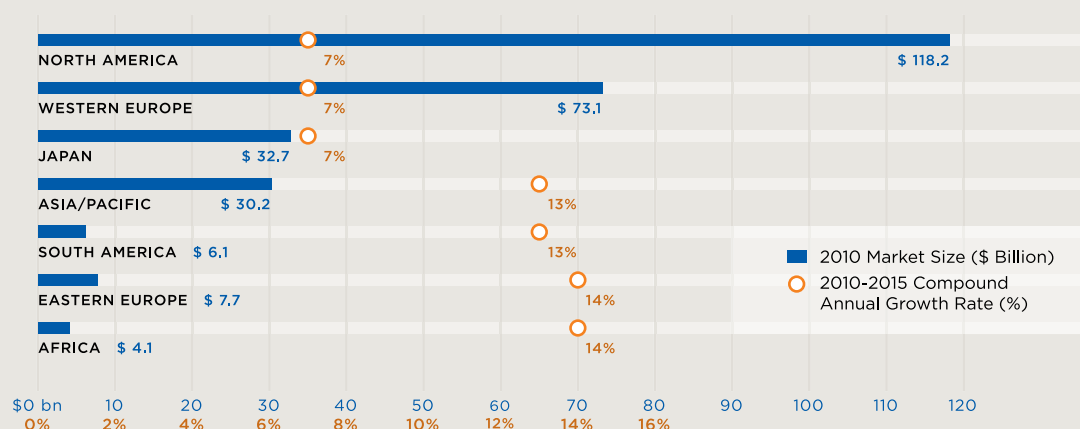
pressure over price and marketing practices can be seen as advocacy for better deal terms; the donations and discounts described above reflect companies' response.

Key trends within the health technology sector are changing the basis for this assumption. Aging populations, changing disease burdens, and the effects of the financial crisis have led traditional health systems to scrutinize costs as never before. Countries are asking hard questions about the incremental value of new technologies. Outcome-based reimbursement decisions are gaining in popularity, as reflected in the actions of such agencies as the National Institute for Health and Clinical Excellence in the U.K. and the Institute for Quality and Efficiency in Health Care in Germany. At the same time, R&D productivity has fallen, particularly for pharmaceutical firms. The proportion of total 2009 sales from drugs launched in the prior five years was below 7 percent.²⁵ Average investment per new and approved drug has quadrupled between 2000 and 2009, reaching around \$4 billion.²⁶

In parallel, newly recognized market opportunities are emerging around the enormous unaddressed health needs of low- and middle-income countries. Many Asian and African countries, in particular, face a double burden of infectious disease and increasing rates of non-communicable diseases (NCDs), such as cardiovascular disease, diabetes, and cancer. NCDs in low- and middle-income countries caused half of all deaths worldwide — around 34 million — while 96 percent of all deaths due to infectious diseases also occurred in those nations.²⁷ Meeting the needs of these countries represents one of the biggest opportunities for the health technology sector in the coming years.²⁸



For example, the medical device markets in India, China, and Vietnam are each growing at more than 10 percent per year, and are forecast to be worth more than \$20 billion by 2015.²⁹ Brazil, Russia, India, and China are expected to more than double their pharmaceutical spending, rising from \$90 billion in 2010 to \$194 billion in 2015.³⁰ IMS forecasts that spending on medicines will grow at 13 percent to 16 percent per year from 2010 to 2015 in 17 high-growth markets, including

Figure 5: Global Medical Device Market: Value and Growth Rate by Region

Source: "Market Report: World Medical Device Market," Acmite Market Intelligence, 2007

China, India, Brazil, Indonesia, Vietnam, South Africa, and Pakistan.³¹ By comparison, global spending on medicines is forecast to grow at 3 to 6 percent annually through 2015, slowing from 6.2 percent per year over the previous five-year period.³² Overall, analysts forecast that low- and middle-income countries will account for 75 percent of all growth in the pharmaceutical sector from 2011 to 2020.³³

Companies can respond to these disease challenges and market opportunities in a number of ways. For those that can build a competitive advantage in niche, personalized technologies, a continued focus on developed countries may make strategic sense. In most cases, though, corporate strategies in the medical device and pharmaceutical industries will increasingly focus on low- and middle-income countries.

To compete in these markets, companies can continue to act as suppliers, and simply wait for economic growth and strengthened health systems to make their value proposition relevant beyond a small, wealthy elite. Alternatively, they can seize the initiative to reach underserved segments today and grow their businesses. Doing so is not without risk. The rules of competition vary greatly, lack of information makes it difficult to identify and characterize opportunities, and political instability and weak infrastructure hamper execution.

Nevertheless, as shown in this report, companies are confronting these barriers with new approaches. While it is still early, the potential gains — both for society and for companies — are substantial.

SETTING THE CONTEXT: EVOLVING ATTITUDES TO SHARED VALUE AMONG CIVIL SOCIETY AND SHAREHOLDERS

The health technology sector has been subject to significant attention from both civil society and the investment community over the last twenty years. Nonprofit, advocacy organizations have had a long-running dialogue with the sector, often sharply criticizing the lack of effective engagement to meet the needs of the underserved. Shareholders have valued the consistent, high returns that many firms have been able to generate, but have shown little interest in long-term opportunities in low- and middle-income countries. These attitudes have set the context for corporate decision-making around levels of investment and quality of engagement in meeting global health needs. As shared value opportunities for health technology companies have become more evident, attitudes are changing, albeit with some important caveats.

Civil Society

Pharmaceutical firms have had a mixed relationship with civil society — far more tense than medical device firms. For the pharmaceutical industry, engagement on global health issues is interpreted through the historical lens of HIV/AIDS. HIV/AIDS activists played a key role in demanding change from the industry, and pharmaceutical companies' reticence to support expanded access led to a reputational crisis. In more recent years of the epidemic, the industry responded with many partnerships to support the treatment of HIV/AIDS and other infectious diseases. This legacy of battles over HIV/AIDS makes some pharmaceutical companies overly cautious regarding involvement in global health issues, particularly where the underserved in low- and middle-income countries and potential profits are involved.

Many issues still remain contentious. Organizations like Oxfam International and *Médecins Sans Frontières*

highlight a lack of R&D for neglected diseases and observe that many life-saving medications remain financially out of reach for the poorest people. The greatest ongoing criticism focuses on intellectual property. In particular, critics cite the pharmaceutical industry's defense of its patents and its challenges to governments that use emergency mechanisms made available through TRIPS (Trade-Related aspects of Intellectual Property Rights). Such mechanisms force companies to offer licenses to produce their medicines.

As demonstrated in this report, the health technology sector has shared interests in strong health systems, disease awareness among patients and providers, efficient distribution, and fair rules around competition. As companies move toward more sustainable, strategic solutions to improve access to medicines in low- and middle-income countries, old mindsets may change.

To understand the changing perspectives about pharmaceutical and medical device firms, FSG partnered with the Global Health Council (GHC) to conduct an online survey of its members, which it administered in August 2011. These global health actors see pharmaceutical and medical device companies as important partners in meeting global health needs. An overwhelming majority of respondents (79 percent) believe that companies in these industries are important contributors to their mission, and are open to engaging with companies (see Figure 6).

Respondents see these industries as making global health issues a priority, because of their business relevance, not just their image-enhancing benefits. Sixty-two percent of respondents believe that the industries view global health issues as relevant from a commercial perspective,

while 32 percent believe that they view global health issues from a reputational perspective.

Respondents indicated that a company's actions related to product safety and access had the most impact on their reputation. In contrast, philanthropic contributions and employee engagement activities — and surprisingly, even new products — did not have as strong an influence.

Figure 6:

Importance of Companies to Respondents' Mission

How do pharmaceutical and medical device companies fit with your organization's mission?

(N=126)



Source: FSG-Global Health Council Survey, 2011

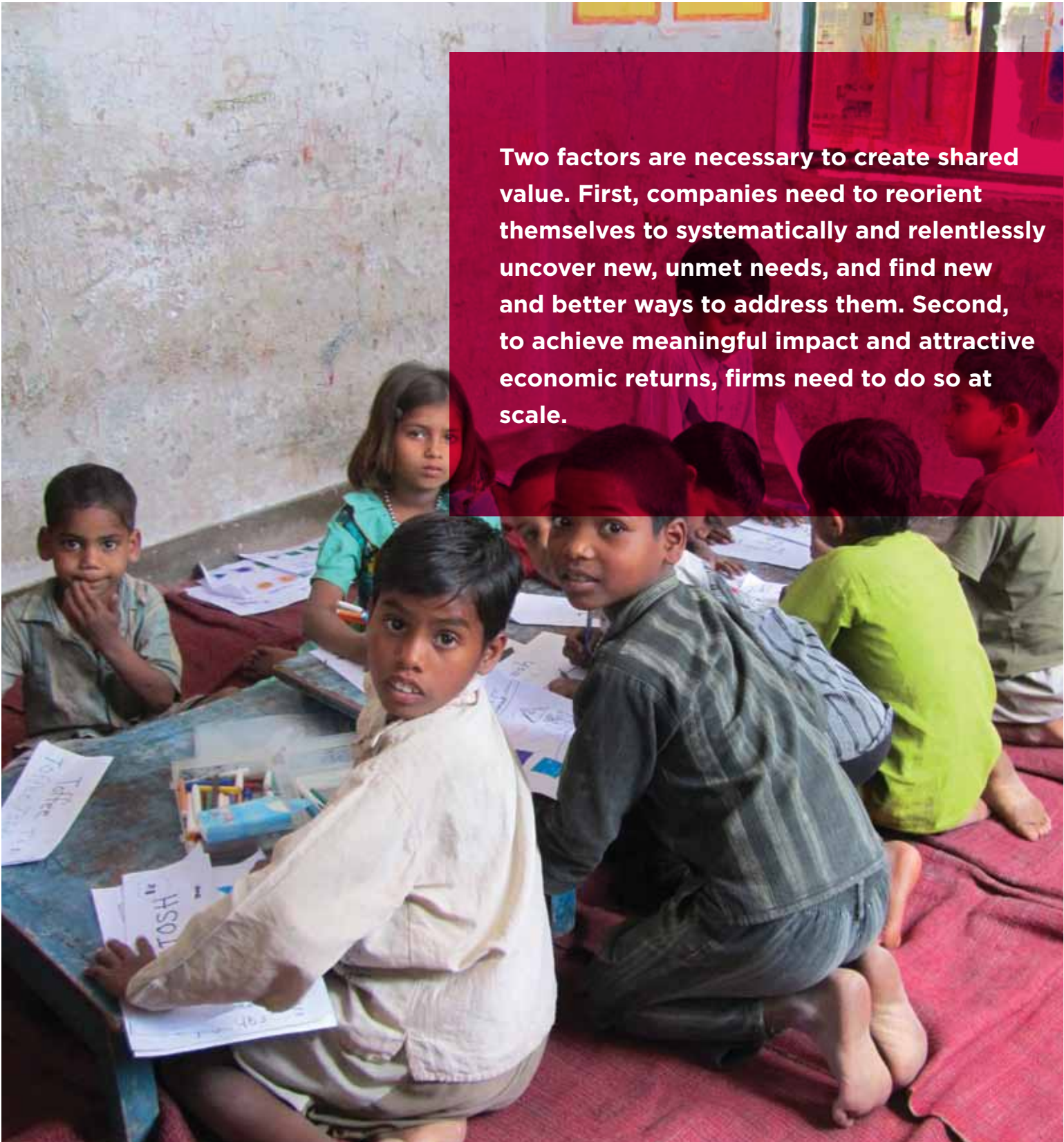
Shareholders

Currently, the investment community (with the exception of socially responsible investment analysts such as Henderson, Aviva, and others) pays minimal attention to health technology firms' engagement in global health. The first mainstream analyst report to touch on the subject, published by UBS, appeared in 2010.³⁴ For the most part, shareholders and analysts are adopting a wait-and-see approach to how companies address low- and middle-income markets.

As companies move toward shared value in global health, and their efforts begin to contribute significantly to financial results, this is likely to change. Indeed, UBS pharmaceutical analyst Gbola Amusa believes that penetration into emerging markets will start to be a driver of European companies' share prices as early as 2012, as the effects of patent expirations work their way through the system (though it may take longer for American firms).

Early movers in the investment community, such as the Pharmaceutical Share Owners Group, have already begun to recognize the opportunity that unmet health needs represent. The coalition of socially-minded investors had an important influence on getting access to medicines issues onto the boardroom agendas of pharmaceutical companies. The PharmaFutures series of investor dialogues has paid increasing attention to this question, focusing on emerging markets in its third publication in 2008 and on shared value in its fourth publication in 2010. In May 2011, 29 institutional investors, who together manage \$3.7 trillion in assets, signed a statement, developed with the Access to Medicine Foundation, stating that they considered pharmaceutical companies' efforts to reach the underserved "potentially material to long-term shareholder value creation."³⁵

Shared Value Opportunities in Global Health

A photograph of a group of young children, likely in a classroom or community center, sitting on the floor. They are looking at papers and drawing. The children are of various ethnicities and are dressed in casual clothing. The background shows a wall with some posters or drawings. A semi-transparent red box is overlaid on the right side of the image, containing text.

Two factors are necessary to create shared value. First, companies need to reorient themselves to systematically and relentlessly uncover new, unmet needs, and find new and better ways to address them. Second, to achieve meaningful impact and attractive economic returns, firms need to do so at scale.

Companies create shared value in global health when they compete on the basis of improving health outcomes for the underserved.

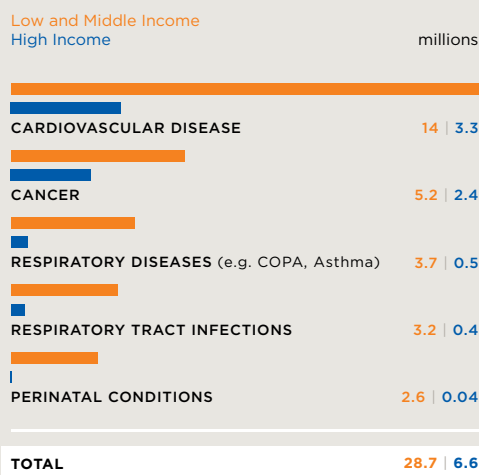
Rather than competing for market share among well-funded payers and wealthy patients, companies view their success in terms of their ability to improve health outcomes by building and serving new markets. To achieve that success, companies must think differently about how they run their businesses.

Two factors are necessary to create shared value. First, companies need to reorient themselves to systematically and relentlessly uncover new, unmet needs, and find new and better ways to address them. Second, to achieve meaningful impact and attractive economic returns, firms need to do so at scale.³⁶

Low- and middle-income countries have vast unmet needs. In 2010, 34 million people were living with HIV/AIDS, two-thirds of whom were in Sub-Saharan Africa.³⁷ Low- and middle-income countries account for nearly 80 percent of the burden from such NCDs as cardiovascular disease, diabetes, cancer, and chronic respiratory diseases, which together caused 63 percent of all deaths

in 2008.³⁸ Estimates put the number of people in Asia, Africa, and Latin America suffering from asthma in 2004 at more than 130 million, with particularly high rates reported in Peru, Brazil, and South Africa.³⁹ More than 55 percent of the nearly 13 million cancer cases recorded in 2008 were in low- and middle-income countries; by 2030, those countries are expected to account for two-thirds of an estimated 21 million cases.^{40,41} Seventy percent of the estimated 285 million people with diabetes in 2010 lived in these nations, and diabetes rates are expected to nearly double by 2030, with low- and middle-income countries seeing the largest increases.⁴² In India and China, diabetes, heart disease, and stroke are expected to cost more than \$750 billion from 2005 to 2015.⁴³ Overall, estimates suggest that NCDs could cost more than \$30 trillion over the next 20 years and could lead to a global loss of output of \$47 trillion.⁴⁴

Figure 7:
Top Five Non-Injury Causes of Death in 2008



Source: Causes of Death 2008, World Health Organization

Addressing unmet health needs in these markets will not be easy, even for companies that excel at innovation, market adaptability, and stakeholder management. While most of the conversation about the private sector's role in global health has centered on gaps in upstream R&D activities, many of the problems to overcome are downstream, delivery-based challenges. Five key barriers to scaling business in low- and middle-income countries are identified in the literature: missing skills and knowledge, limited market information, ineffective regulation, inadequate infrastructure, and limited access to financial products and services.⁴⁵ In addition to these factors, health technology firms are challenged to adapt their often complex products for countries with limited resources or patient ability to pay. Local health systems also may not be capable of delivering their products safely and effectively.

Companies are addressing these barriers through specific approaches across three levels of shared value that have an increasingly external emphasis. First, companies can **reconceive their products and markets**, devising new ways of addressing unmet health needs and developing more affordable and appropriate products. Second, they can **redefine productivity in the value chain**, to reach underserved groups affordably and at scale. Third, they can **enable local cluster development**, strengthening the systems, infrastructure, and context that allow products to be delivered competitively and sold widely.

Figure 8: Levels of Shared Value Creation for the Health Technology Sector

1 Reconceiving Products and Markets	2 Redefining Productivity in the Value Chain	3 Enabling Local Cluster Development
<ul style="list-style-type: none"> • R&D for drugs, vaccines, and devices that fill unmet health needs • Adaptation of existing products to reduce complexity and cost • Tailored product offerings to meet local market conditions 	<ul style="list-style-type: none"> • Collaborative and homegrown R&D to reduce cost and risk • Efficient, local supply chains and manufacturing to reduce production costs • Locally-adapted sales and distribution to penetrate new markets and better meet patient needs 	<ul style="list-style-type: none"> • Behavior-change campaigns to increase the sophistication of demand for health care • Health system strengthening to enable delivery of needed products and services • Advocacy and capacity building to strengthen policy and the regulatory environment

Corporate efforts to reconceive **products and markets** are perhaps the most advanced across the three levels of shared value (see Table 1). Many firms have adopted tiered or discounted pricing for poor consumers.⁴⁶ In addition, companies are redeveloping existing product lines to meet the needs of these new markets, either by lowering unit costs or improving functionality in resource-poor environments. The most compelling initiatives are the result of companies thinking more broadly about the needs and behaviors of specific segments of the population, and developing ways to address them affordably and at scale. In general, successful approaches are **patient-centered, affordable, and tailored to local conditions**.

Table 1: Reconceiving Products and Markets

Area of Activity	Approaches	Examples
R&D for drugs, vaccines, and devices that fill unmet health needs	<ul style="list-style-type: none"> New technologies for diagnosis, prevention, or treatment New delivery mechanisms 	<ul style="list-style-type: none"> Daiichi Sankyo, through its generics subsidiary, Ranbaxy Labs, partnered with the Indian government to develop new tuberculosis drugs Boehringer-Ingelheim developed extended-release, once daily Viamune® (nevirapine) for HIV treatment that aims to replace twice daily, immediate-release tablets of nevirapine, reducing the pill burden
Adaptation of existing products to reduce complexity and cost	<ul style="list-style-type: none"> Re-engineering / reformulation to improve functionality Redesign to lower unit cost 	<ul style="list-style-type: none"> Dr. Reddy invested in a cardiovascular disease polypill, the “Red Heart Pill” which combines several products and could be widely distributed to lower the risk of the disease GE, through its healthymagination platform, developed an ECG machine suitable for mobile use in difficult environments (see company profile) Medtronic developed a leadless pacemaker that can be monitored remotely, where seeing a specialist regularly can be difficult (see company profile) Abbott’s True Care business in India launched a combination of two antibiotics specifically developed to address the issue of drug-resistant typhoid
Tailored product offerings to meet local market conditions	<ul style="list-style-type: none"> Product portfolio selection Tiered pricing Adapted packaging to reduce unit cost or improve safety 	<ul style="list-style-type: none"> Novartis selected a portfolio of patented, generic, over-the-counter and consumer products for its Arogya Parivar business in rural India (see company profile) GSK set prices for its patented products in the least developed countries at a maximum of 25 percent of the price in the U.K. or France Merck KGaA, Johnson & Johnson and GSK are working with technology company Sproxil to roll out a mobile phone-based drug authentication system in Nigeria, Kenya and India; May & Baker Nigeria is working with HP and mPedigree on a similar system GSK repackaged its Ventolin® asthma medication from a 200-dose pre-filled inhaler at \$5 each to packs of two to three doses retailing for just a few cents

COMPANY PROFILE

GE's healthmagination initiative was founded as a platform to coordinate research and development across the company, with the aim of launching products that would lower-cost, enhance quality, and expand access. The company set ambitious targets of investing \$3 billion to develop more than 100 healthmagination products that would improve on cost, quality, and access targets by 15 percent each by 2015.

Establishing healthmagination in May 2009 was an essential step in setting the broad corporate focus on in-country, for-country innovation. The company recognized that, given the highly localized nature of health needs, it needed to give local teams the independence to innovate inside a market, for that market. The company's view was that reverse innovation demanded a decentralized, local-market focus — one that fundamentally conflicts with the centralized, product-focused structure that for years had been the standard way to compete globally. Local teams in China, India, and other emerging markets were given unprecedented autonomy to innovate for their markets. By taking an experiment-and-learn approach, the teams spent a little and learned a lot.

GE saw a need to grow its business in India, as the country represented only 2 percent of GE Healthcare's revenue in 2010. GE also noted the rapid growth in cardiovascular disease in the country, including the 70 percent of people living in rural areas, who may not have consistent access to electricity. The company developed its MAC line of electrocardiogram (ECG) machines, a more portable and affordable version of the common cardiac diagnostic device to extend access to rural areas. The machines have simplified operations, run on a highly efficient battery, and sell for as low as \$500, compared with GE Healthcare's hospital-based units, which can cost tens of thousands of dollars more. GE has sold 10,000 of the units to date, with individual physicians purchasing 90 percent of the ECGs so far. GE leaders cite the importance of proximity to local markets in facilitating the adaptations needed to innovate in emerging markets.

GE:

Adapting Existing Products to Reduce Complexity and Cost⁴⁷





As companies learn how to deliver reconceived products to new markets, investments to **boost value chain productivity** will become more common (see Table 2). Innovative partnerships are emerging to share the risks and reduce the costs of R&D, such as ViiV Healthcare. Firms are experimenting with a range of new approaches to improve the efficiency and reliability of their manufacturing and sourcing. Gilead, for example, has entered into licensing contracts with 12 Indian active pharmaceutical ingredient manufacturers, which has reduced its supply costs by 67 percent.⁴⁸ Companies like Abbott, Novartis, and Stryker are also developing increasingly effective and differentiated approaches to sales and distribution.

The potential for shared value is by no means limited to health outcomes. Companies interviewed for this paper noted positive effects on local job creation in particular.⁴⁹ From a health perspective, though, the main opportunity for shared value lies in aligning the value chain to deliver on the promise of well-adapted, affordable products and services. Successful investments in this area **improve reliability, reduce costs, and leverage local expertise.**

Table 2: Redefining Productivity in the Value Chain

Area of Activity	Approaches	Examples
Collaborative and homegrown R&D to reduce cost and risk	<ul style="list-style-type: none"> Investment in new or existing local research institutions Collaborative approaches to reduce cost and share development risk 	<ul style="list-style-type: none"> Stryker hired and trained indigenous R&D talent to develop India-specific products (see company profile) Novo Nordisk established an R&D center in China, allowing it to tap into the knowledge of Chinese scientists to develop locally-appropriate insulin products Hilleman Labs, a joint venture between Merck and Wellcome Trust, was created to develop and bring to market affordable vaccines for low- and middle-income countries Pfizer and GSK created a new, jointly-owned company, ViiV Healthcare, that combines compounds owned by both firms to create a viable pipeline for new HIV medicines
Efficient, local supply chains and manufacturing to reduce production costs	<ul style="list-style-type: none"> Supply chain strengthening Licensing Local production facilities Improved manufacturing practices 	<ul style="list-style-type: none"> Gilead licensed production of active pharmaceutical ingredients for HIV medication to 12 Indian companies, reducing supply risk and creating price competition to drive down costs (see below) Cipla has established manufacturing plants in Uganda and Sierra Leone in order to better serve markets in Sub-Saharan Africa The Clinton Health Access Initiative improved Aspen Pharmacare and other generic companies' manufacturing processes, established local suppliers of critical reagents, and facilitated new API (active pharmaceutical ingredient) supplier entry to reduce the price of efavirenz (an HIV medication) by 69 percent
Locally-adapted sales and distribution to penetrate new markets and better meet patient needs	<ul style="list-style-type: none"> Sales force reconfiguration New distribution approaches 	<ul style="list-style-type: none"> Abbott has adapted its sales force to reach low-income populations in remote areas of India (see company profile) GSK is working with its distributors to share the risk of switching to a higher volume model to ensure that price reductions are passed on to patients Pfizer's initiative, <i>Comunidad más saludable</i> ("Healthier Community"), in Venezuela trains community sales representatives to target health clinics in low-income neighborhoods to promote Pfizer products, along with discount coupons for patients to increase access

COMPANY PROFILE

Abbott: Adapting the Sales Force to Penetrate India's Remote Areas⁵⁰

When Abbott bought the branded generic drugs business of Piramal, a major Indian producer, it had high expectations. The company anticipated establishing a leading position in the growing, branded generics market in India, which represented \$8 billion in sales in 2011 and is expected to more than double by 2015. Abbott projects more than \$2.5 billion in annual pharmaceutical sales in India by 2020.

To reach these goals, the company needed new approaches to penetrate India's small towns and rural areas, which represent 42% of the pharmaceutical market. A key component in the Piramal domestic formulations purchase was the True Care business unit, which brings high-quality and affordable medicines to people in remote areas of urban and rural India — currently some 10,000 towns and villages.

The unit takes an innovative approach to developing a sales force: It hires sales representatives who are graduates from non-scientific disciplines, have local language skills, and ties to the communities they will target. The company provides intensive training, performance

incentives, and coaching in areas like sales and science.

Local sales representatives are more effective in selling and promoting health in their communities. The sales force conducts a large number of education programs on basic diseases for health care practitioners. More than 38,000 health care practitioners took part in such programs in the past year.

True Care has achieved impressive results. In the last four years, 58 million patients have been reached. However, hurdles remain. The business continues to adapt the product portfolio to address the local disease burden and to find an appropriate balance between profitability and access. In particular, it has been challenging to adapt True Care to Abbott's operational standards, while competing within the local context. Abbott recognizes that driving both growth and access in these markets is a long-term effort that will require new approaches to meet these challenges in the years ahead."



COMPANY PROFILE

A leader in orthopedic care, Stryker set its sights on gaining market share in India five years ago, with an ambition to develop appropriate devices and orthopedic implants locally. The market potential was huge — approximately 80,000 highly arthritic patients forego knee-replacement surgery each year.

The company started with an investment in building indigenous R&D talent. It commonly recruits from such fields as automotive engineering, because existing skills are lacking. The company has provided experiential learning opportunities to its trainees and taught them to seek out health needs. Through a partnership with Stanford's Biodesign group, the Sanjay Gandhi Postgraduate Institute of Medical Sciences, and the All India Institute of Medical Sciences (AIIMS), Stryker's investment in training at its new Global Technology Center has already paid off. One knee system, with proven clinical history, has already been developed and launched at an affordable price for the local market. Stryker hopes that other India-specific

product and business-model innovations will result in more appropriate local solutions. Currently, the country imports up to 80 percent of medical devices.

Stryker's investments in R&D and new relationships have unlocked a key insight — trained surgeons are woefully inadequate and training for knee-joint surgery is nonexistent in the country. Through hands-on training, demonstrations, and a train-the-trainer model, more than 100 surgeons have been trained during the last two years. Now the company is tackling the greatest challenge — health care infrastructure. Stryker is planning to help smaller hospitals throughout the country build high-quality operating rooms with state-of-the-art technology, such as video linkages among operating rooms and with other hospitals so that surgeons can review their work with peers and continue to learn.

Stryker:
Homegrown R&D
for Orthopedic
Care in India⁵¹

Perhaps most interesting from a global health perspective is the growing trend of companies **investing in the clusters** in which they operate. When pharmaceutical and medical device companies invest in health care clusters within low- and middle-income countries — to improve patient awareness and demand, health systems, and the policy and regulatory environment — they not only bolster their own ability to reach new markets, but they also provide value to society that goes beyond the immediate benefit of their medicines or devices to patients.

However, many cluster efforts remain subscale, disjointed, and reactive, addressing acute problems when they arise but stopping short of creating fundamental change. Innovations that could alter the economics of health care provision, such as staged payment schemes and insurance, for example, remain rare. Nonetheless, existing investments in health care systems are likely to grow over time as companies build a presence in the market and begin to understand what works. In general, successful cluster-building efforts **enable the effective and safe delivery of products and services to new populations; improve patient and health system ability to pay; and promote health-seeking behavior**, by overcoming barriers such as lack of knowledge, poverty, or geographic distance to a health care provider.

Table 3: Enabling Local Cluster Development

Area of Activity	Approaches	Examples
Behavior-change campaigns to increase the sophistication of demand for health care	<ul style="list-style-type: none"> • Social marketing to increase health-seeking behaviour by patients • Patient education about disease management 	<ul style="list-style-type: none"> • Eli Lilly's partnership with Population Services International in India will create new awareness about diabetes in two Indian cities (see company profile) • Medtronic's Beijing Patient Care Center educates patients, physicians, and caregivers about cardiovascular therapies to address the lack of time that physicians have with chronic disease patients
Health system strengthening to enable delivery of needed products and services	<ul style="list-style-type: none"> • Improvements to infrastructure and to the capacity of management and staff • Financing innovations in insurance and payer coverage 	<ul style="list-style-type: none"> • AstraZeneca invested in provider training and awareness to increase breast-cancer treatment in Kenya (see company profile) • Through its Amplicare program, Roche is training health professionals on the use of innovative new diagnostics • Sanofi-Aventis is working with the microfinance organization, PlaNet Finance, to develop microloans that support antimalarial purchases in Madagascar
Advocacy and capacity building to strengthen policy and the regulatory environment	<ul style="list-style-type: none"> • National guideline development • Regulatory capacity and efficiency 	<ul style="list-style-type: none"> • Novo Nordisk and the World Diabetes Foundation worked with the Chinese Ministry of Health to improve case management guidelines for diabetes (see company profile) • Abbott worked to build the capacity of Chinese regulatory authorities to assess and approve the contents of nutritional products

While companies often start with one shared value approach — reduced prices for example — they frequently discover barriers and opportunities that demand complementary shared value investment.

Gilead Sciences provides an example of how a company that starts with one activity, in this case licensed manufacturing, can uncover a need for complementary investments in other shared value approaches. As the company behind several antiretroviral drugs containing the chemical tenofovir, Gilead broke new ground with its licensing approach that allowed for large-scale manufacturing of tenofovir-based products by Indian generic manufacturers. Through voluntary licenses to 12 generic companies operating in India, the price of these products in low-income countries has dropped dramatically, and 1.8 million patients living with HIV now use tenofovir-based products.

COMPANY PROFILE

Of the nearly half-million deaths from breast cancer in 2008, 64 percent occurred in low- and middle-income countries.⁵³ Breast cancer is a complex disease to treat, as it requires individual specialist attention and regular visits to a hospital or other health facility. Delivering breast-cancer care and treatment in resource-constrained settings is especially challenging as these locations lack disease surveillance, awareness of the disease, and specialists. The cost of treatment can also be out of reach for most patients.

Against this backdrop, AstraZeneca recently launched *Pambazuka* (“Sunrise”) to expand access to breast-cancer treatment in Kenya, where fewer than 20 percent of potential patients are ever treated. Through careful analysis of the country’s referral system, the company identified the root causes of this low treatment rate: lack of awareness of symptoms and treatment options among patients and health workers, poor access to quality diagnosis, and a relatively high cost of treatment. *Pambazuka* aims to address these barriers by providing one-day breast-cancer management workshops for surgeons, doctors, and nurses in Kenya’s

three largest cities. Working with the Africa Cancer Foundation, the program also aims to strengthen patient support and awareness by providing one-day trainings for volunteers and counselors who are involved in patient care. In addition, AstraZeneca has significantly reduced the price of its breast-cancer products — lowering the price of Arimidex 59 percent and Nolvadex 32 percent — in order to make them more affordable.

Though the program is still at an early stage and measurable results are not yet available, it still aims to be profitable as it is based on a similar initiative that AstraZeneca launched last year in South Africa. AstraZeneca seeks to learn from its experience with *Pambazuka* to develop similar programs in other developing countries where the increasing cancer burden is posing a significant challenge to health care systems that typically have not been set up to provide treatment for chronic conditions.

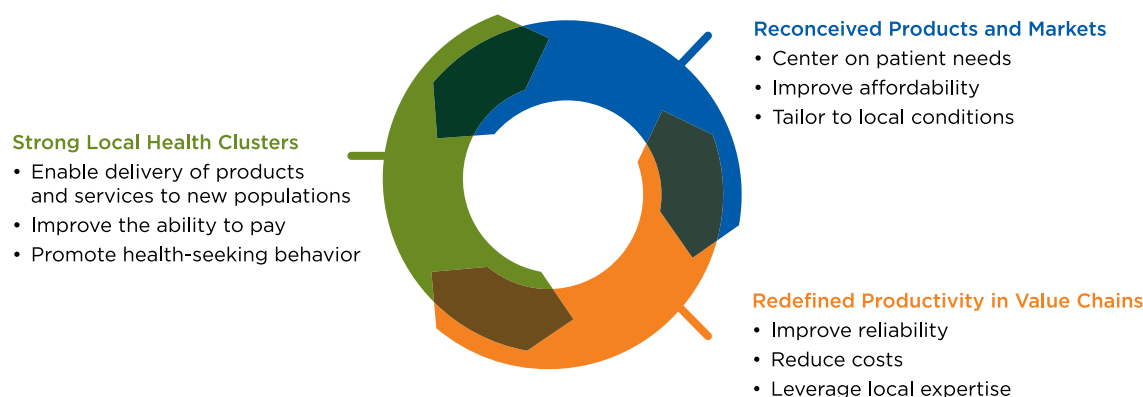
AstraZeneca: Health System Strengthening to Pilot Breast-Cancer Treatment in Kenya⁵²

The initiative is now profitable as the company collects a small royalty from the sale of generic copies of its products.

Gilead also retains the ability to sell its branded products. To increase uptake and support for its 11 distributors operating in 132 countries, Gilead identified the need for local cluster development through patient and provider educational materials, treatment guidelines, and inventory management tools. The company is providing the necessary information to local ministries of health and piloting an SMS-based mHealth platform called HIV Link that allows rural community health care workers to communicate with HIV experts via mobile phone.

Efforts to create shared value across the three levels are also mutually reinforcing (see Figure 9). Productive and lower-cost value chains are essential to connecting redesigned product portfolios to underserved markets. Strong clusters can enable firms to serve population segments that were previously out of reach, and can open up new, lower-cost manufacturing and distribution options.

Figure 9: Efforts to Create Shared Value are Mutually Reinforcing



Leading firms are beginning to design multi-level approaches to harness this multiplier effect. Medtronic, for example, is investing in redesigned devices for use in resource-poor settings, diagnostic capabilities to ensure they are used appropriately, and advocacy to increase global attention to the non-communicable diseases. Stryker also started with product R&D but is now investing in its cluster through surgeon training and equipping small hospitals with improved operating rooms in India. GSK, Novartis, and Novo Nordisk each employ a combination of approaches across all three levels of shared value.

The right combination of shared value approaches will be unique to a particular company and market. Factors such as disease burden, payer dynamics, regulations, health system strength, and cultural attitudes to health care vary both between and within countries. For a company like GSK, with a competitive advantage in vaccines, working through the GAVI Alliance to reach the underserved populations in the 48 least developed countries makes strategic sense. For others, such as Roche, whose strength lies more in complex-to-administer oncology drugs, middle-income segments in more developed countries (that are nonetheless underserved) are a more relevant starting point.

Identifying the specific populations that companies are best placed to serve can be challenging. Market data and analytics are incomplete and hard to find.⁵⁶ The definition and classification of unmet needs varies from country to country.⁵⁷ Nevertheless, companies must apply their expertise

COMPANY PROFILE

Medtronic's business model traditionally focused on the development and marketing of medical devices in North America and Europe.⁵⁵ In recent years, the company shifted to a strategy that prioritizes expansion in low- and middle-income countries. The company launched the Medtronic Global NCD Initiative with a target of reaching 25 million patients per year by 2020. Most of this growth will be in treating NCDs and their complications. Achieving its goal will require investments in all three approaches to shared value, and a major shift in the company culture. The company's product offerings must be reengineered to fit lower-tech health systems. For example, seeing a specialist regularly is difficult in many poorer countries. Innovations like a leadless pacemaker that can be monitored or controlled remotely therefore have significant

potential to enhance the quality of care, and could also be implanted with less invasive procedures. Other product reengineering opportunities being explored include lower-cost disposable insulin pumps, and new drug delivery approaches for Alzheimer's disease.

Medtronic also sees a need to improve the clusters associated with upstream diagnosis and care. Executives at Medtronic's cardiac business in India realized that the primary access challenge was related to diagnosing the need for a pacemaker, not in the device itself. The company partners with organizations attempting to bridge this gap, such as Maestros, a provider of telemedicine-based EKG interpretation services that will improve access to cardiac screening.

Medtronic:
Adaptation
of Existing
Products Leads
to Health System
Strengthening⁵⁴

in segmentation and innovation to these new markets to uncover the most promising opportunities and design effective strategies to seize them.⁵⁸

As companies penetrate more deeply into lower income and rural markets in India, China, Brazil, and South Africa, or in least developed countries such as Kenya, more barriers are confronted. To address these barriers and move further into the shared value frontier, companies will further innovate and adopt more comprehensive strategies that utilize approaches within all three levels of shared value creation.

Some companies are expanding the shared value frontier. In rural India, for example, Novartis aims to expand the reach of Arogya Parivar to 100 million people. GSK India employs more than 100 staff dedicated to expanding its penetration into rural areas, and is investing in strengthening the health infrastructure in six states to support this process. Similarly, Sanofi-Aventis and GSK are already starting to explicitly add least developed countries to their business focus. Building on its success in China, Novo Nordisk is considering taking a focused approach to diabetes in a range of developing countries including Bangladesh and Nigeria.

GENERICS COMPANIES: AFFORDABLE PRODUCTS, EFFICIENT VALUE CHAINS, BUT LIMITS TO SHARED VALUE⁵⁹

Generic pharmaceutical manufacturers are better placed than their traditional, R&D-led counterparts to create shared value in global health in several ways. Due to efficient, local supply chains and manufacturing, they can keep operating costs low and local production volumes high, which often allows them to price more competitively than R&D-led firms. It may also be easier for them to compose a broad product portfolio, since many are able to source or manufacture a wide range of compounds, while traditional pharmaceutical companies may be optimized for those chemical entities and therapeutic areas for which they hold patents. As a result, generics companies often enjoy a competitive advantage in developing tailored product offerings that align with local market conditions in low- and middle-income countries.

However, generics companies' ability to beat traditional firms on price also makes them significantly less well-placed to work in other ways. Most lack the capability or investment capital to conduct R&D for new technologies that fill unmet health needs. Moreover, smaller generics manufacturers have little footprint outside their home markets, and may therefore struggle to develop competitive, locally-adapted sales and distribution channels. Of 12 low- and middle-income country-based generics companies analyzed by IMS in 2011, 9 generated more than half their revenues from their domestic markets.⁶⁰ Also, their relatively thin margins mean they may have limited capacity to invest in strengthening the cluster in order to expand their markets and reach new patients.

These differences are beginning to blur as the structure of the industry changes. Leading generics companies are moving into territory in which traditional pharmaceutical

companies have enjoyed an advantage. Leading generics firms have begun to invest in product development capabilities, initially focused on adaptation of existing products to reduce complexity and cost. Dr. Reddy, for example, leveraged its ability to manufacture a broad range of chemicals to formulate its single-dose Red Heart Pill, which is easier to administer correctly. Cipla is moving into unpatented biopharmaceuticals through the production of "bio-similars" with even the possibility of "bio-betters", drugs better than the originators, in addition to development of CFC-free inhalers, a new delivery mechanism.^{61,62}

Additionally, the industries themselves are converging. Two different types of generics companies can already be discerned: commodity manufacturers that continue to compete exclusively on price, and larger "branded generics" firms that seek to build trusted brands for which they can charge a premium. Many generics companies have entered supply alliances with originals manufacturers to provide active pharmaceutical ingredients or to manufacture patented medicines locally under license. Finally, there has been a wave of recent mergers, such as Daiichi Sankyo's purchase of Ranbaxy or Sanofi-Aventis' acquisition of Zentiva. Indeed, 6 of the top 10 generics manufacturers are also leading traditional R&D-led firms, with a collective global market share of 20 percent by value.⁶³

COMPANY PROFILE

In 2007, Novartis launched a new initiative called Arogya Parivar (AP), which focuses on rural Indians earning between \$1 and \$5 per day. It has set a goal of developing a sustainable, scalable business to reach this underserved group. In designing the business, Novartis carefully analyzed the local disease burden, and developed a tailored portfolio of affordable medicines, drawing from its originals, generics, and over-the-counter businesses. It recruited local sales teams to work in areas where workers knew the culture and spoke the dialect, providing access to crucial market intelligence and reducing mistrust among potential customers. In parallel, Novartis invested in an arm's-length program for community health education, in order to tackle the chronic lack of health-seeking behavior that it had identified as a key barrier.

Rural India is a massively underserved health market. While approximately 70 percent of the Indian population lives outside urban areas, they account for just 22 percent of health spending and many do not seek formal health care at all. Among those who do seek health care, people commonly wait to visit a clinic or hospital until a condition becomes acute, rather than seeking treatment more quickly. More than two-thirds of health spending is out-of-pocket.

Not all of the challenges were well understood at the beginning. In particular, the company initially underestimated the extent to which infrastructure issues would impede growth. The unreliability of the supply chain reduced patients' trust in the system and willingness to return for care, so Novartis invested in developing a dense network of local distributors, in order to reduce stock-outs. Through the Credit for Health Initiative, it is also working with local microfinance partners to counter a lack of finance that was limiting the development of new clinics and health providers. Finally,

to bridge the infrastructure gap in the short term, AP organizes frequent health camps to bring physicians into rural areas. In addition to expanding health care access, these camps can provide an additional sales channel for AP's portfolio of products (the choice of medicine is at the doctors' discretion and not limited to Novartis products), as well as a small source of income for the doctors who participate.

Four years since its inception, the initiative is beginning to see real results. It broke even in its 31st month of operation and is now generating profits. Nascent evidence is emerging about improved health outcomes, although the company acknowledges that more work is required for effective measurement. To date, the initiative covers 42 million people in 33,000 villages across 10 Indian states. After the health camps arrived, doctor visits in these villages tripled, from 9 percent to 23 percent of local populations.

Novartis has ambitious plans to scale and replicate AP, and has created the Social Business Group to oversee the process. Within India, the company has set a goal of reaching 100 million people in 100,000 villages across all 23 Indian states over the coming years. It is also seeking to replicate the model in other Asian and African countries, starting with Kenya and Vietnam. The firm recognizes that only some of what has been learned in India is applicable elsewhere, and that its efforts must be tailored to each new location. While low levels of health-seeking behavior are expected to be a common challenge, the method of addressing this problem will differ according to local needs, regulatory environments, and cultures. Similarly, the product portfolio will need to be aligned with local disease burdens and market structures, and in Kenya's case, with a lower ability to pay.

Novartis:
Overcoming
Barriers in Rural
India⁶⁴

COMPANY PROFILE

Novo Nordisk:

Early Engagement on Diabetes Treatment in China⁶⁵

Novo Nordisk was one of the first Western firms to enter the Chinese insulin market in 1994. By 2010, the company had grown its market share to 63 percent (about 13 percentage points higher than its global share) in what has become a \$1 billion market. It has saved an estimated 140,000 life years in the process. Early engagement across all three levels of shared value has contributed to this success.

The company has invested heavily in developing appropriate products that are well adapted to local needs. Its first local production facility

government to develop and update national standard treatment guidelines. It has instituted a far-reaching physician-training program for diabetes diagnosis and care, both directly through its sales representatives and in partnership with the WDF and Chinese government. It has also pursued a high-profile awareness campaign to help improve patient management of the disease.

Beyond China, Novo Nordisk has identified a range of developing countries, including India, Bangladesh, and Nigeria, where a similar, comprehensive diabetes strategy may be viable. Finally, in China itself, it sees significant potential: 70 percent of Chinese diabetics are still not diagnosed, and of those that are, just one in 10 successfully manages

Beyond China, Novo Nordisk has identified a range of developing countries, including India, Bangladesh, and Nigeria, where a similar, comprehensive diabetes strategy may be viable.

opened in Tianjin in 1995, allowing it to gain production efficiencies and respond more quickly to market demand. In 2002, it was the first non-Chinese pharmaceutical company to establish an R&D center in China, which has allowed it to gain a competitive advantage through improved market understanding. In addition, the R&D center allows it to tap into a highly qualified talent pool of Chinese scientists, many of whom have returned from leading universities around the world to work in China.

Novo Nordisk has also invested in a broad range of cluster-strengthening initiatives. It worked with the World Diabetes Foundation (WDF), a nonprofit created and partly funded by the company, as well as with the Chinese

his or her condition. Changing these numbers holds enormous promise for both Chinese society and Novo Nordisk's shareholders.

COMPANY PROFILE

Through its Developing Countries and Market Access business unit (DCMA), GlaxoSmithKline (GSK) is among the few companies researched for this report that are directly seeking to build a business in the world's least developed countries (LDCs). DCMA was created in 2010 and reports to the company's Emerging Markets division. The group is still relatively small: It currently accounts for around 3 percent of total emerging markets revenues. However, it has ambitious expansion plans, owing to GSK's competitive advantage in vaccines, antibiotics, and anti-infectives. The company intends to grow annual sales volumes from 60 million dose equivalents of these and other key products in 2010 to 300 million by 2015.

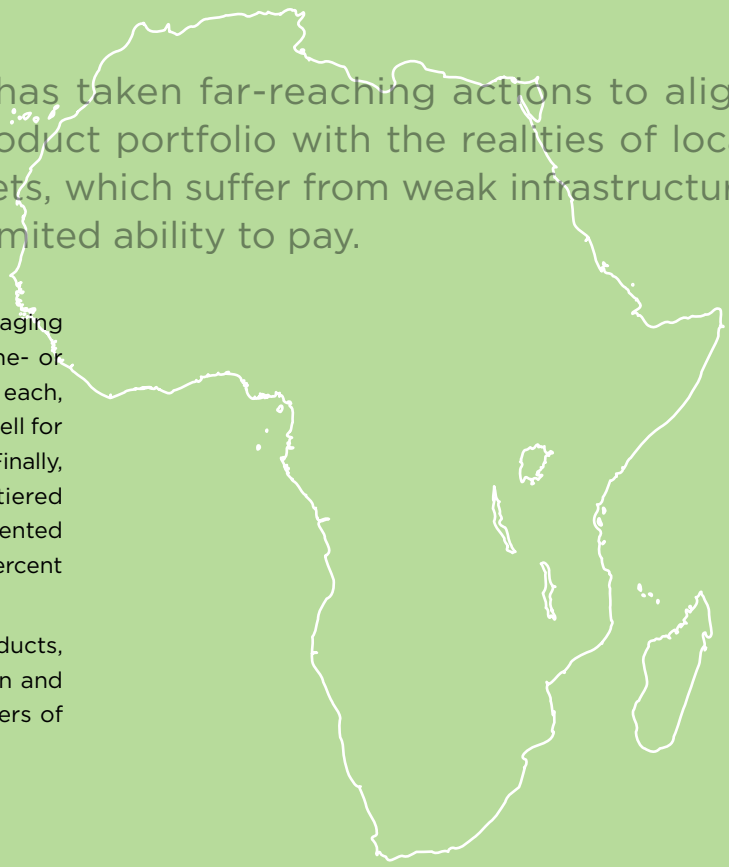
GSK has taken far-reaching actions to align its product portfolio with the realities of local markets, which suffer from weak infrastructure and limited ability to pay. The company is working to repackage or reformulate existing products — for example, packaging its Ventolin® asthma medication in one- or two-dose units that sell for a few cents each, rather than the 200-dose inhalers that sell for around \$5 each in developed countries. Finally, the company is an industry leader in tiered pricing: It has committed to sell its patented products in LDCs for no more than 25 percent of the price in the U.K. and France.

To support the delivery of targeted products, the company is adapting its value chain and making investments in the health clusters of

LDCs. Local sales personnel are increasingly offered incentives based on volume, rather than incentives traditionally based on revenue. It is experimenting with risk-sharing agreements with distributors in several African countries. As new, lower-cost products are being rolled out, the company is working with its distributors to ensure that price reductions are passed on to patients. Also, GSK has committed to reinvest 20 percent of the profits generated in LDCs into health systems and infrastructure, including clinics and training for health professionals.

GSK's DCMA business unit expects to contribute around \$300M to the company's top line in 2015.

GlaxoSmithKline:
Platform for
Shared Value in
Least Developed
Countries⁶⁶



GSK has taken far-reaching actions to align its product portfolio with the realities of local markets, which suffer from weak infrastructure and limited ability to pay.

BRIDGING THE SHARED VALUE FRONTIER THROUGH CORPORATE PHILANTHROPY AND FUNDER INCENTIVES

Although shared value has the potential to address many global health needs, there will always be populations or locations that are beyond the reach of commercial approaches, where market failures exist. It is unlikely that the companies mentioned in this report will find pure commercial approaches for the underserved in locations like Haiti, Sierra Leone, or rural areas of Tanzania. Companies also find it difficult to invest in R&D for some neglected diseases, such as schistosomiasis or chagas disease.

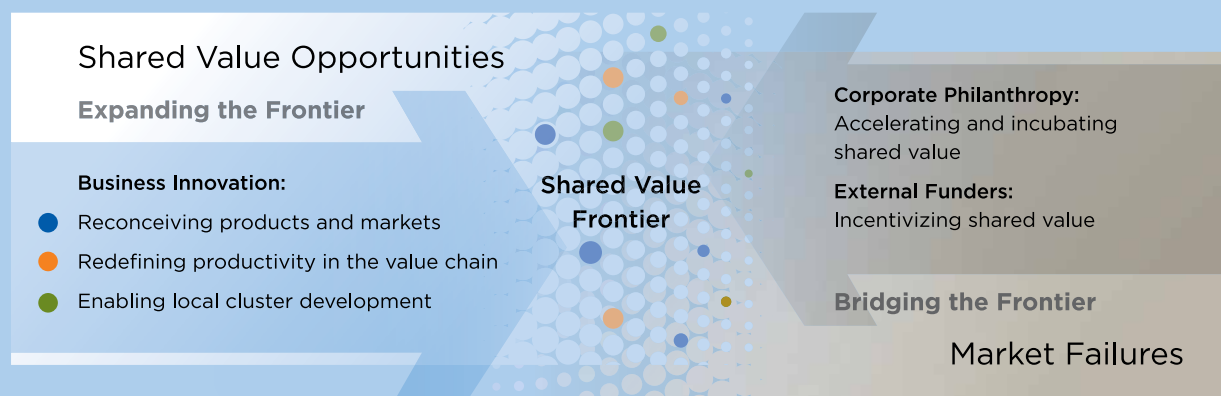
But, companies are exploring innovative ways to further expand opportunities in the **shared value frontier** — the area that borders market failure. Here, shared value opportunities are less viable in the short-term but can improve with the passing of time and economic progress. Due to low sophistication of demand for health services by patients or lack of health care infrastructure, companies may need to invest to a greater degree by innovating across multiple levels of shared value. In

addition, companies are utilizing two methods — corporate philanthropic contributions and funder incentives — to overcome barriers and bridge the shared value frontier (see Figure 10).

In addition to more traditional philanthropy that has been ubiquitous within the health technology sector for decades, corporate philanthropy is now accelerating and incubating shared value. Likewise, governments and foundations recognize the health technology sector's assets and expertise and are providing cash and in-kind incentives to unleash corporate R&D, marketing, and manufacturing resources for diseases and populations of the developing world.

These types of bridging arrangements are relatively new. They mark new areas of opportunity for companies and global stakeholders to work together on product development, value chain enhancement, and local

Figure 10: Bridging the Shared Value Frontier



cluster-building where there might not be immediate commercial rationale.

Accelerating and Incubating Shared Value through Corporate Philanthropy

The pharmaceutical and medical device industries have given billions in charitable contributions, through cash and product donations, disaster relief, and ongoing health programs. Pharmaceutical companies, in particular, are among the largest corporate donors in the world: Merck's total cash giving and product donations amounted to \$1.16 billion in 2010.⁶⁷ Companies featured in this report lead initiatives that leverage core assets, such as donated medicines and R&D expertise, through such programs as the Pfizer-supported International Trachoma Initiative and the GSK-supported Global Alliance to Eliminate Lymphatic Filariasis, to name a few. Companies have worked strategically in targeted countries — Abbott in Tanzania, Pfizer in Uganda, and Merck in Botswana. Such programs have reached millions of patients and provided care that would not otherwise have been delivered. They have also evolved, adding other funders to reduce dependency, codifying lessons, and focusing on capacity-building, particularly among government partners.

But the role of corporate philanthropy in addressing global health challenges is changing even more profoundly as companies recognize philanthropy's shortcomings and identify new shared value opportunities. Companies are now adopting a portfolio of corporate philanthropy approaches that are tailored to diseases and population groups. Where there are existing commercial interests, companies can **accelerate** shared value. In places where companies do not yet have commercial interests but may have in the longer-term future, they can **incubate** shared value. More traditional corporate philanthropy, in the form

of product donations, volunteered time, and program support, will certainly continue for the poorest patients.

Companies accelerate shared value through corporate philanthropy by enabling the development of local clusters relevant to their business. When companies provide charitable support to local clusters, they can upgrade the capabilities of local health workers, increase demand for



treatment, or even improve national guidelines for care. Eli Lilly's NCD Partnership uses corporate-giving dollars to strengthen health systems in India, Brazil, South Africa, and Mexico. In two Indian cities, the company intends to increase the number of patients diagnosed with diabetes through mass media awareness campaigns and screening events. Nonprofit implementing partners will also train physicians, pharmacists, nurses, and community-based health care workers to improve diabetes care and treatment. Philanthropic investments that accelerate shared value integrate with other, more commercial, approaches and are intended to provide both societal and economic benefits. For Eli Lilly, the company has a strategic interest in growing its insulin business in a market that has one of the highest burdens of diabetes.

Companies also leverage their corporate philanthropy programs to incubate shared value opportunities in future markets or for diseases that have a longer time horizon for profitability. The Medtronic Foundation makes grants to organizations like Partners in Health to develop models for diagnosing and treating NCDs in less developed countries, such as Rwanda, where the company does not have a commercial presence. In this case, the Foundation acts independently but supports issues of future importance to the business, such as integrating NCDs into primary health care systems.

By their nature, these corporate philanthropic investments are not company-specific, and competitors will also be lifted by the rising tide. The company taking the lead may reap differential benefits through capturing lessons or

funding multi-company initiatives to support frontline health workers in Southeast Asia and Africa and new medical school curricula for the next generation of global health leaders.

The increasing focus on shared value is not a substitute for strategic forms of corporate philanthropy that address diseases, treat patients, or build health systems in locations that are the least developed. Patients in rural locations of Malawi or Tanzania do not have the financial resources to purchase medicines or devices, and health care systems are often non-existent. Companies can continue to focus on their greatest asset — the nonfinancial resources of expertise, networks, and influence — to advance these initiatives in partnership with local actors and with a sustainability strategy in place from the outset.

Incentivizing Shared Value through Funder Collaboration

Governments, foundations, and multilateral organizations can accelerate movement along the shared value frontier through incentives to bridge market failures. Significant innovation has taken place over the last decade, with an emphasis on partnership incentives to spur corporate R&D for neglected diseases. Several approaches have emerged or are in an experimental phase:

- International organizations like the GAVI Alliance have used Advanced Market Commitments (AMCs) to give vaccine manufacturers certainty that if they invest in development and achieve certain efficacy standards, they can be guaranteed a certain market volume and price. In the AMC for pneumococcal vaccines, for example, a \$2.8 billion funding commitment led GSK and Pfizer to enter the market. They will now sell as many as 300 million doses each by 2023.⁶⁸

developing relationships. But this dynamic could make co-investment by multiple companies, even competing ones, feasible and desirable. For example, to support its strategic emphasis on NCDs in low- and middle-income countries, the Medtronic Foundation gave a \$1 million grant to the NCD Alliance. Several other companies followed with additional funding. The Foundation is now



- Prize mechanisms reward the development of technologies within a set of criteria. Today most are not at the scale necessary to influence major companies, but examples include the Tuberculosis Diagnostic X-Prize and the point-of-care fever diagnostic proposed by BIO Ventures for Global Health.

- Product development partnerships (PDPs) are nonprofit organizations that build partnerships among private and government funders, companies, and academic institutions to reduce the financial risk of R&D for products used in low- and middle-income countries. To date, these efforts have

been largely focused on the pharmaceutical rather than the medical device industry, with the Foundation for Innovative New Diagnostics (FIND) being the exception. A few successful products have launched, such as Coartem Dispersible, an artemisinin-based combination therapy (ACT) to fight malaria in children, developed by Novartis and Medicines for Malaria Ventures. Companies also dedicate specific R&D capacity to work with these nonprofit partners. GSK's site at Tres Cantos in Spain, the Novartis Institute of Tropical Diseases in Singapore, and AstraZeneca's Bangalore Research Institute are significant commitments of R&D capacity. As the shared value frontier advances, these investments may become powerful sources of future competitive advantage.

- The FDA's Priority Review Voucher program rewards companies for R&D focused on neglected diseases with a transferrable voucher that accelerates the review of another of the company's products. The use of tax credits as a fiscal incentive is also being explored. Genzyme proposed a 50 percent credit on

non-clinical expenses for neglected-diseases research to help take some risk out of R&D, although a recent analysis by Results for Development Institute calls for a more aggressive measure to create R&D incentives.⁶⁹

- To reduce the price of existing products, health organizations like UNITAID and BioVentures for Global Health have created patent pools (for HIV and neglected tropical diseases, respectively) that

Governments, foundations, and multilateral organizations can accelerate movement along the shared value frontier through incentives to bridge market failures.

would license intellectual property rights to lower-cost manufacturers, giving originating companies a royalty and fostering greater competition. Other proposals, such as a Health Impact Fund, would compensate companies for the actual health improvements that their products create, strengthening the link between impact and business value.

Implementing Shared Value in Global Health

Shared value represents a corporate-level strategic choice to compete on the basis of serving unmet global health needs. As seen from the menu of approaches featured in this report, shared value holds implications for how functions across the company, from R&D to marketing, prioritize their investments and activities.



Several companies interviewed for this paper have embarked on significant organizational change to implement shared value initiatives. While few have completed this process, five key principles guide their efforts (see Figure 11).

Figure 11: Five Principles for Shared Value Implementation in Global Health

- 1 Focused and determined leadership at the CEO and country levels**
- 2 A culture of innovation and learning reflected in structures and incentives**
- 3 New approaches to measurement that track the link between business value and patient lives improved**
- 4 New skills in identifying and acting on unmet health needs**
- 5 New partnerships for shared value insights and implementation**

1 >

Focused and Determined Leadership at the CEO and Country Levels

Almost every company interviewed for this paper spontaneously mentioned strong leadership as a key success factor. It is no coincidence that those firms that have been most successful in competing on the basis of meeting global health needs enjoy the energetic involvement of the CEO. GSK's Sir Andrew Witty has articulated a corporate strategy to move beyond "white pills in Western markets," and has been closely involved in the creation of that company's Developing Countries and Market Access group. GE's Jeffrey Immelt personally launched the firm's healthy-magination strategy; managers describe his role as key to engaging other business units in the strategy.

In addition to strong direction from the corporate center, leadership is essential within individual country affiliates and business units, since shared value actually gets created at this level. While the support of Novartis CEO Joe Jimenez spurred the decision to establish a presence in rural India, it is the dedicated work of Anuj Pasrija, head of Novartis' Social Business Group, and his team that built the company's Arogya Parivar business.

COMPANY PROFILE

Eli Lilly & Co.:

Overcoming Obstacles to Shared Value Implementation⁷⁰

The experience of Eli Lilly and Company demonstrates how a company new to shared value needs to invest up front in strategy development and in aligning internal operations.

Lilly had a strong history of philanthropic contributions, first in areas relatively separate from its core business, such as education, and later through more aligned commitments like the Lilly MDR-TB Partnership, which included technology transfers and anti-tuberculosis drug licensing. Simultaneously, the company prioritized emerging-markets growth. A 2009 restructuring elevated the importance of the emerging-markets business unit, and countries like India have goals of tripling revenue in the next five years. Given the business targets, the company needed its engagement on global health issues to evolve as well.

As an entry point into shared value, the company launched the Lilly NCD Partnership, an effort to improve diabetes care in key low- and middle-income countries. The partnership will strengthen local clusters immediately, benefiting the company and people with diabetes, as well as generating longer-term knowledge through research.

In developing the initiative, the company encountered several implementation challenges. When Lilly staff had previously considered opportunities to reinvent the company's involvement in diabetes care in new markets, they found themselves going against the grain of conventional thinking about the company's contribution to society — specifically, that social engagement should be separate from the business. As senior leaders in the company

developed a deeper understanding of the potential to create shared value, the idea of a more aligned approach gained traction. But it took deep engagement and leadership from the head of corporate affairs, to the diabetes and emerging markets business units and up to the CEO, to achieve this shift.

The company also needed to balance central strategies with country ownership: The initiative is being launched in India, South Africa, Mexico, and Brazil, all countries where Lilly has a strong local presence. This local involvement meant balancing central strategic coherence from headquarters with the specific local situations, relationships, and opportunities that the local affiliate presented — and also required substantial time for sharing ideas and gaining alignment.

The development of the initiative took more than a year of planning, but Lilly leaders emphasize how crucial that up-front investment was to overcome the challenges of shifting to a new strategy.

2 >

A Culture of Innovation and Learning Reflected in Structures and Incentives

Innovation and learning is essential to creating shared value in global health. Without a culture that embraces entrepreneurial risk-taking, companies may miss opportunities to reach underserved populations in new ways, only to see those opportunities seized by bolder competitors. Corporations can build such a culture by adopting structures that offer managers the autonomy and authority to innovate while promoting firm-wide learning, and by aligning incentives with long-term value creation.

Two organizational models for promoting a culture of innovation and learning are emerging. A number of companies have established a **cross-functional team** with a mandate to expand efforts company-wide. Typically these units function as coordinators, informing how other parts of the company implement strategies. GE's healthymagination initiative serves as a central node for innovations to expand access, decrease cost, and improve quality — but product managers within other GE business units or outside partners administer product R&D. At BD, a global health team develops partnerships and identifies product opportunities related to health needs in the least developed countries, but ultimately other business units execute on these ideas. For some companies, such as Medtronic in its work on NCDs, these coordinating bodies are also a mechanism for engaging the corporate foundation while ultimately keeping core responsibilities on the business side.

A second model for organizing to create shared value is a **separate innovation unit that directly manages initiatives**, usually in conjunction with country affiliates. Several leading companies have created walled-off units charged with developing innovative strategies to reach new markets. Novartis, for example, manages Arogya Parivar through a separate Social Business Group, rather than through its Indian affiliate. This approach provides room for Novartis to experiment, without affecting operating structures or incentives in other parts of the Indian business. GSK's Developing Countries and Market Access group represents a similar implementation approach. Such dedicated business units create space to innovate around shared value, free from short-term sales pressures that could undermine efforts to reach new customer segments. They also help to ensure a stable base of resources for investment in shared value initiatives.

Financial and non-financial performance incentives also have an important influence on managers' ability and willingness to focus on solving new health challenges. For example, several companies interviewed reported that, traditionally, professional success hinges on achieving measurable results during a two- to three-year management rotation. These incentive patterns can make it difficult for managers to find and pursue shared value opportunities that may take longer to demonstrate a return on investment. Now, companies are starting to create new systems that align individuals' incentive structures with elements important for shared value. In many cases, this has shifted incentives from margins to volumes as the primary metric of success.

3 >

New Approaches to Measurement that Track the Link between Business Value and Patient Lives Improved

Innovation and learning depend on measurement that captures the link between economic value creation for the business and improved health outcomes for patients. An understanding of what works allows companies to assess the potential of new investments to create shared value, and provides a basis to allocate resources and set incentives.

Several companies are leading the way in measuring their work. GE works with the consultancy Oxford Analytica to assess the cost, quality, and access implications of its product innovation. The assessment considers factors like the marginal improvement in diagnosis accuracy rates, as well as the cost savings for a local health system if better diagnosis results in more streamlined treatment. On the business side, product managers assess sales potential in the same way they would evaluate any GE Healthcare product, although with hurdles that use adjusted rates of return in some cases. To date the process has resulted in 45 products that are attractive business opportunities for GE and achieve healthymagination's goals of 15 percent improvements on cost, quality, and access.

Novo Nordisk has calculated a net present value for itself, and for Chinese society, of better disease management in diabetic patients. The company calculates that improving patient control over diabetes — through better diagnosis, appropriate treatment, and ongoing disease management — is worth around \$2,350 to Chinese society over the lifetime of a patient in an urban area. It is also worth around \$3,400 per patient to Novo Nordisk in increased treatment sales. If China could help the estimated 16 million people with diabetes in large urban centers to exercise greater control over their disease, it could have a net present value of some \$37 billion to the country. Moreover, if Novo Nordisk were able to maintain around a 60 percent market share, such an improvement could have a net present value of as much as \$30 billion to the company.⁷¹

These metrics allow Novo Nordisk to allocate resources based on an informed expectation of potential returns. The company also tracks the contribution of specific initiatives toward achieving overarching goals, in order to adapt and improve its efforts. For example, the company discovered that training physicians in small cities had a 9 percent greater effect on treatment management than training their counterparts in larger cities.

4 >

New Skills in Identifying and Acting on Unmet Health Needs

To implement shared value strategies, many companies are changing how they define responsibilities and hire for roles, emphasizing hybrid backgrounds and skills. In addition to managing sophisticated commercial operations, country managers are often expected to be thought leaders on health needs in their respective countries.

Companies are also investing in the professional development of existing staff. Novartis and GSK both use leadership-development programs to create opportunities for promising talent to spend

COMPANY PROFILE

BD (Becton, Dickinson and Co.) is an example of how a company starting from an evaluation of unmet health needs and philanthropic involvement in global health can expand to a more holistic shared value strategy.

BD has engaged in a range of public-private sector collaborations on global health issues. HIV was a particular area of focus: BD engaged with the US President's Emergency Plan for AIDS Relief (PEPFAR) on issues like laboratory-capacity strengthening and safer blood collection, and with the Clinton Health Access Initiative to expand access to CD4 diagnostic testing. BD entered into these agreements from a socially motivated commitment to global health, and leaders stress the importance of authenticity of purpose, integrity, and trust-building in forming collaborations. What makes the BD experience different from traditional corporate social responsibility is how the company learned from these experiences to identify opportunities for market expansion and product innovation, allowing it to further advance global health outcomes while also generating substantial business value.

As the company assessed the landscape of infectious disease in Sub-Saharan Africa in the early 2000s, it identified product and training

needs vital to supporting the global response to HIV/AIDS. Areas of focus included laboratory system strengthening, safe immunizations of children, access to diagnostic testing in district and rural settings, and safe blood handling. These efforts led to the creation of collaborative programs and tailored product engineering. Developing a firsthand understanding of the gaps in existing health systems helped the company pursue new program- and product-development activities to serve unmet needs. Its new products would ultimately be relevant not only to the sites of their public-private collaborations in Africa, but also to a more global market.

An intentional structure and process enabled these opportunities. A Global Health group coordinates company involvement in these issues and collaborates directly with BD's product teams. Ultimately, the process of committing the company's resources to fulfill broad social needs has infused a "new management science" into the company as a whole. Its operating model of deep involvement in public-private sector collaborations in countries like Kenya and Zambia is now informing how the company engages to address health needs in China and other low- and middle-income countries.

BD:

Learning From Unmet Health Needs⁷²

time thinking creatively about strategic problems associated with serving low- and middle-income countries. A significant number of pharmaceutical firms, including Pfizer, Abbott, Eli Lilly, and GSK, have well-known skill-based volunteering programs in low- and middle-income countries that have a similar sensitizing and experiential learning effect on employees.

5 >

New Partnerships for Shared Value Insights and Implementation

Health technology companies have had a long history of engaging with organizations that set the context for global health. As mentioned earlier, various stakeholders have communicated expectations for the sector in terms of R&D priorities, access to medicines, and intellectual property. Low- and middle-income country governments create or foster the policy, regulatory, and health system environments. Organizations like WHO, Oxfam, and MSF continue to exert major influence in global health policy. Likewise, as mentioned above (see “Bridging the Shared Value Frontier”), external funders have also played an important role in providing incentives to stimulate companies to act in ways that might not otherwise be in their short-term commercial interest. Two new types of partners are appearing as shared value initiatives gain momentum: insight and information providers and implementation partners.

Figure 12: Roles of Shared Value Stakeholders

Role	Description	Examples
Context Setting Organizations	<ul style="list-style-type: none"> Shape the environment within which companies operate, including regulation, guidelines, health system organization, norms and expectations 	<ul style="list-style-type: none"> Local governments Coordinating authorities Regulatory entities Advocacy organizations Industry associations Investment analysts
Information & Insight Providers	<ul style="list-style-type: none"> Conduct market research and analysis, or offer advice and expertise, to provide information and insights that industry has difficulty accessing 	<ul style="list-style-type: none"> Nonprofit organizations Global health consulting firms
Implementation Partners	<ul style="list-style-type: none"> Work directly on the development or delivery of products, services, or other investments, to provide implementation capabilities that companies lack 	<ul style="list-style-type: none"> Nonprofit organizations Product development partnerships Industry competitors Local health systems
Funders	<ul style="list-style-type: none"> Provide overseas development aid and philanthropic funds to bridge market failures in global health 	<ul style="list-style-type: none"> Foundations Multinationals Governments

Two new types of partners are appearing as shared value initiatives gain momentum: insight and information providers and implementation partners.

Information and insight providers play a vital role in helping companies develop and execute shared value strategies. They plug gaps in knowledge, expertise, and insight. Groups like the Access to Medicine Foundation, IMS Health, Broadreach, Axios, and IDEO support companies as they analyze new-product opportunities, design access approaches, and assess the strength of the surrounding health system.

Implementation partners work with companies across all three levels of shared value, as shown in the examples featured below:

- **Reconceiving products and markets:** The nonprofit organization PATH has for years partnered with companies on R&D to address diseases in the developing world. Increasingly, the organization looks for alignment with companies' business interests when establishing partnerships. For example, it saw a clear market for a low-cost Japanese encephalitis vaccine, but needed a producer to work with. Chengdu Institute of Biological Products, a Chinese manufacturer, wanted to enter the more lucrative export market, but needed technical assistance to meet international quality standards. PATH was an effective partner since it understood the company's business drivers, and now the company is selling 135 million doses of vaccine to the Indian government at affordable prices. Companies are also forming partnerships with other companies, such as the agreement between Tibotec and Gilead to develop and commercialize a new once-daily, single-tablet, fixed-dose antiretroviral combination product that uses Tibotec's Prezista and Gilead's Cobicistat products.
- **Redefining productivity in the value chain:** The Clinton Health Access Initiative (CHAI) works with manufacturers of antiretrovirals, antimalarials, diagnostics, and other health technologies to help companies reduce production costs. By focusing on efficiency improvements, cost reductions for active pharmaceutical ingredients, and the predictability of demand, CHAI has facilitated dramatic price reductions of these technologies, particularly with HIV treatments, while creating business opportunities for companies. In another example, the for-profit firm Moksha8 partners with pharmaceutical companies to market and distribute products in Latin America in exchange for a percentage of sales. Its model pursues a higher-volume approach for drugs facing generic competition, which traditional pharmaceutical strategies might see as no longer viable. With Pfizer's antibiotic Vibramycin, for example, the partnership led to 40 percent greater sales than Pfizer's projections.⁷³
- **Enabling local cluster development:** Novartis started SMS for Life, an initiative that uses mobile phones and SMS technology to manage the supply of artemisinin-based combination therapies and quinine injectables to reduce stock-outs, in conjunction with the Roll Back Malaria Partnership, IBM, Vodafone, and the Ministry of Health in Tanzania. The successful Tanzania pilot has led to current efforts to scale the model in other countries.

Catalyzing Greater Shared Value for Global Health

Creating shared value is not a panacea for all global health challenges. Some efforts will inevitably disappoint, and market failures will remain. Nevertheless, pharmaceutical and medical device companies have an extraordinary opportunity to help reduce global suffering and ill-health by building a competitive advantage in the low- and middle-income countries that will underpin future industry growth.



This study has charted the shared value journey of health technology companies for the benefit of business and global health. But the movement is just beginning, as both industries still focus their attention on premium markets in North America, Europe, and Japan. Significant barriers, including corporate mindsets and challenging environments in low- and middle-income countries, are slowing greater investments in shared value initiatives. The following recommendations for companies and stakeholders can catalyze greater experimentation in shared value for the benefit of companies, patients, and health systems.

Recommendations for Companies



Shift from defensive to affirmative engagement with patients in low- and middle-income countries.

Companies should be transparent with global stakeholders about their ambitions in low- and middle-income countries. Specific shared value approaches, motivated by profit, can be articulated for the benefit of the global health field. Where shared value approaches are not presently feasible, companies can explain the role of their philanthropic contributions and the intentions of partnerships with government and private funders. These clarifications are important as global health stakeholders are often confused about the motivations of companies in low- and middle-income countries and how the various activities — commercial, philanthropic, or incentivized partnerships — fit within their overall corporate strategies. Likewise, companies are not always clear as to what constitutes appropriate types of investments for fear of appearing to make a profit from underserved patients.

More affirmative shared value positions can change the present dynamic of stakeholder engagement. All the companies mentioned in this report have elaborate global stakeholder engagement systems that require time and effort to manage. Stakeholder engagement should evolve to include candid dialogue about what is and is not possible to serve underserved patients. Stakeholders can be a source of proactive learning about patient needs and health system requirements, rather than targets for public relations messages.

Industry associations, such as the Pharmaceutical Research and Manufacturers of America (PhRMA), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), and the Advanced Medical Technology Association (AdvaMed) can be helpful in driving more authentic partnerships with stakeholders. While the tone is changing, these associations still tend to view company partnerships through the lens of philanthropy and reputation. Instead, they should be trumpeting the shared value initiatives of leading companies, thereby accelerating the trend.



Innovate and capture knowledge on health product delivery.

As companies learn more about how to meet the needs of hard-to-reach, poorly served populations, lessons should be shared, within the limits of competitive confidentiality. Companies should work with stakeholders to create a catalog of case studies, since the delivery of health products is critical for them, too.

R&D portfolio management processes are elaborate, structured, measurable, and standardized. The same cannot be said for the delivery of health technologies to underserved populations in low- and middle-income countries. Although many are experimenting, few companies, or other global health actors, for that matter, have a deep understanding of what it takes to deliver drugs and medical devices into resource-constrained settings. Even fewer understand how to do this in multiple country settings.⁷⁴

A good model for emerging knowledge on the subject is the International Partnership for Innovative Healthcare Delivery, led by Duke Medicine, McKinsey, the World Economic Forum, and a handful of pharmaceutical and medical device companies.⁷⁵ The initiative is actively assessing and promoting health product delivery models employed by the private, public, and nonprofit sectors. Initiatives like the Global Health Delivery Project, a partnership among the Harvard School of Public Health, Harvard Business School, Harvard Medical School, and Brigham & Women's Hospital, could be additional sponsors or repositories of knowledge on private sector-driven health care delivery.⁷⁶



Experiment with shared value measurement to spur learning and innovation.

Pharmaceutical and medical device companies should be in a position to lead other industries on measuring shared value, due to the inherent alignment between the increased sales of their products and improved health. Measurement allows companies to show how they make money as they reduce the burden of disease. Such metrics could ignite a cascade of reinforcing benefits, as companies more quickly move beyond their saturated markets, deepen knowledge about new patients, and develop appropriate shared value strategies to meet the special needs of patient segments.

Companies can start measuring health impact in modest, exploratory ways. Companies should set specific, forward-looking targets for populations, behavior changes, health system strengthening and disease indicators, and should measure progress toward them.

While companies can experiment individually, the best path may be a consortium of companies that cooperate on a framework for measurement. While such cooperation is rare in the health technology sector, the results would benefit each company and establish the pharmaceutical and medical device industries as partners in global health.

Investors are a key consumer of such information. Measurement of shared value will shine more light on new markets for investors, increasing their understanding and appreciation for the activities highlighted in this report.



Invest early to gain first-mover advantage.

Making shared value investments is difficult and risky, and returns may take time to accrue. Novo Nordisk spent a decade building its presence in China, but has been rewarded with a market share of more than twice its nearest competitor. Similarly, GSK's strong market position in India stems in part from having been in the market since the 1920s, in addition to its relevant product portfolio. Sanofi-Aventis enjoys similar legacy advantages in West Africa. Those companies that invest early will, therefore, likely find themselves with a sizable competitive advantage as new markets develop and mature.

Recommendations for Global Health Stakeholders

- ➔ *Context-Setting* entities need to monitor the evolution toward shared value. Specifically, advocacy-oriented organizations have a role to play in ensuring that health technology companies develop strategies to expand access to poorer patients at the frontier of shared value in Africa and Asia. Governments can reach out to companies to complement the public sector's role in health care provision.
- ➔ *Information and Insight Providers* can stimulate more immediate shared value opportunities through patient research, value chain analysis, and health system auditing. The Access to Medicine Index, for example, can add more business results metrics like product volumes sold, as well as case studies that show how companies are addressing the barriers mentioned in this report.
- ➔ *Implementation Partners* can be more proactive in offering their services to companies. The product-development and cluster-building services of PATH, Population Services International, and CARE are relatively new to pharmaceutical and medical device companies. For the most part, these organizations are still viewed as philanthropic grantees rather than value-added partners in shared value initiatives.
- ➔ *Funders* like the Bill & Melinda Gates Foundation, the UK Department for International Development, and others have supported R&D partnerships to bridge the shared value frontier. In comparison to R&D, fewer incentives exist to spur company involvement in the actual delivery of products. As companies expand their reach among poor populations in low- and middle-income countries, opportunities may exist to incentivize the private sector to scale-up delivery.



Conclusion

Creating shared value is not a panacea for all global health challenges. Some efforts will inevitably disappoint, and market failures will remain. Nevertheless, pharmaceutical and medical device companies have an extraordinary opportunity to help reduce global suffering and ill-health by building a competitive advantage in the low- and middle-income countries that will underpin future industry growth. Firms that engage in this area can become engines of progress for the global health field. They can be engaged partners rather than neutral suppliers. We hope this report serves to illustrate the scale of that opportunity, and triggers discussion and innovation around ways to capitalize on it.

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alphabetized
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